Odesa National Medical University

Medical faculty

Department of Pharmacology and Pharmacognosy

Syllabus of elective discipline "ADVERSE EFFECTS OF MEDICINES"

Scope	4 credits ECTS, 120 hours
Semester, year of study	IV semester, II year of study (Philosophy doctor)
Days, time, place	According to the schedule in the classrooms № 1-5 of the Department of Pharmacology and Pharmacognosy (cycle of pharmacology): Odessa, Olgievskaya 4 str.
Teachers	Rozhkovsky Ya.V., Head of the Department, Doctor of Medical Sciences, Professor; Kresyun V.Y., Academic of NAMSU, Doctor of Medical Sciences, Professor; Antonenko P.B., Doctor of Medical Sciences, Professor; Lobashova K.G., Candidate of Medical Sciences, Associate Professor; Shemonaeva K.F., Candidate of Medical Sciences, Associate Professor; Ostapchuk K.V., Candidate of Medical Sciences, senior teacher; Antonenko K.O., Candidate of Biological Sciences, assistant.
Contact phone	(048) 717-35-45
E-mail	pharmacology@onmedu.edu.ua
Workplace	Odessa, Olgievskaya 4 str., Department of Pharmacology and Pharmacognosy (cycle of pharmacology)
Consultations	Consultations are conducted by teachers of the department according to the schedule: Face-to-face consultations: Thursday from 14.30 to 17.00; Saturday from 9.00 to 13.00 Online consultations: Thursday from 15.00 to 17.00; Saturday from 9.00 to 13.00 https://moodle.odmu.edu.ua/ or via Microsoft Teams / Telegram / viber / Zoom

COMMUNICATION

Communication with PhD candidates will be through face-to-face meetings. In case of transition to distance learning, communication with students will be carried out by e-mail pharmacology@onmedu.edu.ua and programs: Microsoft Teams, Zoom, Telegram, Viber.

COURSE ANNOTATION

The subject of study of the selective discipline are the characteristic side effects of drugs that are observed when used in the range of therapeutic doses; mechanisms of development of side effects; measures to reduce or prevent side effects or prevention of side effects.

Prerequisites: based on PhD candidates' study of normal and pathological clinical anatomy, histology, cytology and embryology, clinical chemistry, general and clinical pathological physiology, microbiology, virology and immunology, pharmacology, general pharmacy and clinical pharmacology, propaedeutics of internal medicine, phthisiopulmonology, which provides integration with these disciplines.

Post-requisites: lays the foundations for the formation of skills to apply knowledge about the side effects of drugs in the process of further study and in professional activities.

The purpose of the course: to master a set of knowledge, skills, skills of rational and safe for human health use of drugs, which should reduce the frequency or prevent the occurrence of side effects during pharmacotherapy for the treatment and prevention of diseases. This will make it possible to plan and carry out one's own research, to solve significant problems in the field of professional activity, science, and the performance of functional duties related to the rational choice of medicines.

The main objectives of the elective course are to provide PhD candidates' with theoretical knowledge about the types, mechanisms of development, causes and clinical manifestations of side effects; signs of drug poisoning, mechanism of action, probable course and ways of prevention and correction of side effects when prescribing drugs; predicting drug-drug interactions, assessing the risk/benefit ratio when using drugs of different pharmacological groups.

Expected results:

As a result of studying the elective discipline, students **should know**:

- Classification and mechanisms of side effects;
- Methods for evaluating the effectiveness and safety of pharmacotherapy;
- Structure and management of the pharmaceutical service in Ukraine;
- Side effects that occur with the use of drugs that affect the CNS, cardiovascular system, blood system, immunity.
- Have the skills to search process and analyze information from various sources;

Students **must be able to**:

- Assess the risk / benefit ratio for drugs;
- Choose safe pharmacological therapy during pregnancy;
- Report the side effects of drugs;
- Recognize the picture of poisoning by drugs from different groups and prescribe appropriate pharmacotherapy of poisoning;
- To introduce scientific data into the educational process and health care practice;
- Publish the results of scientific research

COURSE DESCRIPTION

Forms and methods of teaching

The course will be presented in seminar classes (60 hours) organization of independent work of PhD candidates' (60 hours).

During the teaching of the discipline, the following teaching methods are used: *in seminar classes* explanations, multimedia presentations, situational learning, simulation learning, oral examination, testing, individual tasks, self-preparation with the textbook, independent work with the department's information resource, scientific literature.

The content of the discipline

Topics of seminar classes:

Topic 1. Pharmacotoxicodynamics. Classification of adverse drug reactions. Factors influencing their occurrence.

Topic 2. Principled approaches to assessing the benefit/risk ratio when choosing medicines. Methods of evaluating the effectiveness and safety of pharmacotherapy.

Topic 3. Pharmaceutical service in Ukraine. Legal aspects of pharmaceutical activity in Ukraine.

Topic 4. The system of pharmacological supervision of drug side effects in the world and in Ukraine. Methods of detecting and obtaining information about adverse reactions. Implementation of pharmacovigilance by doctors.

Topic 5. Adverse reactions that occur with the use of drugs that suppress the CNS. Methods of their prevention.

Topic 6. Adverse reactions that occur with the use of drugs that stimulate the CNS. Methods of their prevention.

Topic 7. Adverse reactions of drugs that affect blood pressure and microcirculation, their prevention.

Topic 8. Adverse reactions with the use of cardiotonics. Methods of prevention and treatment of poisoning.

Topic 9. Adverse reactions with the use of antiarrhythmic and antianginal drugs. Methods of prevention and treatment of poisoning.

Topic 10. Adverse reactions of drugs that affect erythropoiesis and circulating blood volume. Methods of their prevention.

Topic 11. Adverse reactions of drugs that affect leukopoiesis and blood clotting. Methods of their prevention.

Theme 12. Side effects of hormonal drugs.

Topic 13. Side effects of antiallergic drugs.

Topic 14. Adverse reactions when using anti-inflammatory drugs.

Topic 15. Side effects caused by antibiotics. Methods of their prevention.

Topic 16. Adverse reactions caused by antimicrobial agents, which are used for special indications.

Topic 17. Adverse reactions of drugs affecting the respiratory organs.

Topic 18. Adverse reactions of drugs used in the treatment of diseases of the gastrointestinal tract and hepatobiliary system.

Topic 19. The procedure and algorithm for submitting information on adverse drug reactions. Medical mistakes when providing information about adverse drug reactions.

Topic 20. Analysis and protection of forms 137/o. Credit class. Final control of mastering the discipline.

Recommended literature

1. Pharmacology [Text] : a textbook for students of higher medical educational establishments of the IV level of accreditation with English as the language of instruction / V. M. Bobyrov, O. M. Vazhnicha, T. O. Devyatkina, N. M. Devyatkina ; Ukrainian Medical Stomatological Academy. - 4th ed., updated. - Vinnytsia : Nova knyha, 2018. - 551 p.
2. Pharmacology [Text] / K. Whalen; contributor: Sh. Anderson, A. K. Birnbaum, N. Carris [et al.] ; ed.: R. Finkel, Th. A. Panavelil, 2015. - 664 p.
3. Betram G Katzung Basic and Clinical Pharmacology, 14th Edition. - McGraw-Hill Medical, 2018.- 1235.
4. Godovan V.V. Pharmacology in pictures and schemes [Text] : in 2 vol. Vol. 1, 2011. - 270 p.; Vol. 2, 2011. – 242 p.
5. Richard A. Harvey PhD, Michelle A Clark PhD, Richard Finkel PharmD and all. Lippincott Illustrated Reviews: Pharmacology (Lippincott Illustrated Reviews Series) Seventh, North American Edition, Pharmacology 7th edition. 2014. 570 p.
6. McGraw Hill. Basic and Clinical Pharmacology (14th Edition). 2022. 578 p.
7. Oxford Handbook of Pharmaceutical. Medicine.Oxford University Press. 2022. 367 p.

Information resources:

1. Resource for predicting drug interactions (based on FDA guidelines) URL: http://www.drugs.com
2. Resource-directory of medicines and forecasting of interpharmaceutical interactions .URL: http://www.medscape.org
3. Resource of medicines "Compendium" http://compendium.com
4. Simplify drug development with bioinformatics and pharmacology data. https://clarivate.com/cortellis/cortellis-drug-discovery-intelligence-pharmacological-data-to-accelerate-drug-development/?campaignname=Preclinical_Search_LeadGen_Paid_LS_Global_2022&campaignid=7014N000001YZGO&utm_campaign=ad-1&utm_source=adwords&utm_medium=paid&_bt=499393990228&_bk=pharmacology&_bm=b&_bn=g&_bg=118156462059&gclid=Cj0KCQjwxveXBhDDARIsAI0Q0x2Vgs65QA2hEj76H4N6L-zWXf1YIi-Rme7wLH2OduPH6N5MTrbmaAYaAqD8EALw_wcB
5. Pharmacology - Useful websites. https://www.qmul.ac.uk/library/library-skills/resource-guides-by-subject/biological-sciences/useful-websites/pharmacology---useful-websites/
6. Resource. Pharmacology Education Project. https://www.pharmacologyeducation.org/resources

EVALUATION

Current control

It is carried out at each seminar session with the help of: testing, structured written works, based on prescriptions, solving situational problems.

The current assessment of PhD candidates' on relevant topics is carried out according to the traditional 4-point system (excellent, good, satisfactory, unsatisfactory).

The value of the assessment is "**excellent**". The PhD candidates' shows special creative abilities, is able to acquire knowledge independently, without the help of the teacher finds and processes the necessary information, is able to use the acquired knowledge and skills for decision-making in unusual situations, convincingly argues answers, independently reveals own talents and inclinations.

The value of the assessment is "**good**". The PhD candidates' is fluent in the studied amount of material, applies it in practice, freely solves problems in standard situations, and independently corrects mistakes, the number of which is insignificant.

The value of the assessment is "**satisfactory**". The PhD candidates' reproduces a significant part of the theoretical material, shows knowledge and understanding of the basic principles; with the help of the teacher can analyze the educational material, correct mistakes, among which there are a significant number of significant ones.

The value of the assessment is "**unsatisfactory**". The PhD candidates' has the material at the level of individual fragments, which are an insignificant part of the study material.

At the end of the course, the current performance is calculated as the average score of all grades received by the PhD candidates' on a traditional scale, rounded to 2 (two) decimal places.

Final control

The study of the academic discipline ends with a test. Credit will be given to applicants who have not missed seminar classes or completed missed classroom classes and have an average grade of at least 3.00.

Control of self-preparation of the students:

The control of self-preparation of the PhD candidates', which is provided by the topic along with the seminar lesson, is carried out during the current control of the topic in the relevant classroom.

Topics of self-preparation of the students:

Topic 1. Clinical aspects and causality of adverse reactions as a basis for their objective assessment. Peculiarities of drug interactions.

Topic 2. Drugs of abuse. Medical and social aspects of drug and drug addiction.

Topic 3. Legislative acts regulating the system of pharmacological supervision of side effects of medicinal products in the world and in Ukraine.

Topic 4. Adverse reactions to psychotropic drugs.

Topic 5. Adverse reactions to cardiotropic drugs.

Topic 6. Adverse reactions to vasotropic agents and agents that regulate blood pressure.

Topic 7. Adverse reactions when using sugar-lowering drugs.

Topic 8. Adverse reactions of drugs used for increased and decreased function of the thyroid gland.

Topic 9. Adverse reactions to the use of steroidal and non-steroidal anti-inflammatory drugs, as well as slow-acting anti-inflammatory drugs.

Topic 10. Adverse reactions when using antihelminthic, antimycotic, antiviral drugs.

Topic 11. Side effects of antituberculosis therapy. State and ways of overcoming drug resistance of the causative agent of tuberculosis.

Topic 12. Adverse drug reactions during the treatment of gastric ulcer.

Topic 13. Medical documentation designed to provide information. Rules and procedure for filling out form No. 137/o. Algorithm for submitting reports on received side effects of drugs. Preparation for credit class.

ПОЛІТИКА КУРСУ
COURSE POLICY

The policy of studying a selective discipline is determined by the system of requirements that the teacher imposes on the PhD candidates' when studying the discipline. Requirements apply to attendance of all types of classes (inadmissibility of absences, delays), rules of conduct in the seminar lesson (active participation, compliance with the required minimum of educational work), incentives and penalties. The policy of the academic discipline is developed taking into account the norms of the legislation of Ukraine regarding academic integrity, the Statute and provisions of ONMedU, other normative documents.

Deadlines and Rescheduling Policy:

Applicants who have attended all seminar classes and have an average grade of at least 3.0 are admitted to the credit class. Unsatisfactory grades and missed classes can be retaken within 2 weeks without the permission of the dean on the days of consultations and exercises, later - with the permission of the dean; in the case of online distance learning - in terms determined and agreed with the teacher**.**

A policy of academic integrity independent performance of all types of work, tasks, and forms of control provided by the work program of this discipline; providing reliable information about the results of their own educational (scientific) activities, used research methods and sources of information; copying and plagiarism are not allowed.

Attendance policy: attendance at seminar classes is mandatory; exceptions are possible only in case of approval of an individual study schedule for an individual applicant. Lateness to classes is not allowed. Missing classes, regardless

of the reason for the absence, the doctoral degree holder makes up for the teacher according to the schedule of consultations and making up for missed classes.

Mobile devices: the use of a mobile phone, tablet or other mobile devices during class is unacceptable (except for the cases provided for by the curriculum and methodical recommendations of the teacher).

Behavior in the classroom: maintaining silence among applicants in seminar classes, a working discussion atmosphere in classes during the survey; compliance with the ethics of academic relationships.