**MINISTRY OF HEALTHCARE**

**ODESA NATIONAL MEDICAL UNIVERSITY**

**Pharmaceutical faculty**

**Department of General and Clinical Pharmacology and Pharmacognosy**

## Syllabus of elective discipline

# THE BASICS OF PHARMACOGENETICS

| | |
|---|---|
| **Scope** | 3 credits ECTS, 90 hours |
| **Semester, year of study** | 9th semester, Vth year of study |
| **Days, time, place** | According to the schedule in the classrooms № 1-5 of the Department General and Clinical Pharmacology and Pharmacognosy (cycle of pharmacology): Odessa, Olgievskaya 4 str. |
| **Teachers** | Rozhkovsky Ya.V., Head of the Department, D.Med.Sci., professor; Kresyun V.Y., academic of NAMSU, D.Med.Sci., professor; Antonenko P.B., D.Med.Sci., professor; Lobashova K.G., Ph.D., associate professor; Shemonaeva K.F., Ph.D., associate professor; Ostapchuk K.V., Ph.D., senior teacher; Antonenko K.O., Ph.D., assistant professor; Al-Nadawi N.D., assistant professor. |
| **Contact information and phone** | (048) 717-35-45 |
| **E-mail** | gnosy@onmedu.edu.ua |
| **Workplace** | Odessa, Olgievskaya 4 str., Department of General and Clincial Pharmacology and Pharmacognosy (cycle of pharmacology) |
| **Consultations** | Consultations are conducted by teachers of the department according to the schedule:<br>Face-to-face consultations: Thursday from 14.30 to 17.00; Saturday from 9.00 to 13.00<br>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 students 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 discipline "The basics of pharmacogenetics" is a hereditary basis of variability of action of the medicines that allows to predict efficiency and safety during medicines prescriptions

**Prerequisites:** “The basics of pharmacogenetics” as a discipline is based on the study of medical biology, physiology, pathological physiology, pharmacology,

clinical pharmacology, propaedeutics of internal diseases, infectious diseases, family medicine, internal medicine that allows disciplines' integration.

**Postrequisites:** paved the basis for the formation of the skills to apply knowledge of pharmacogenetics in the process of further studying and in professional activities.

**The purpose of the course:** to handle a complex of knowledges, skills, capability of rational and safe for human health use of the drugs, considering human genetic polymorphism, which should reduce the frequency or prevent the occurrence of the adverse effects, as well as improve the effectiveness of the diseases treatment.

**The main tasks of studying the discipline** "The basics of pharmacogenetics" is to provide to the students a theoretical knowledge about the human hereditary mechanisms, which determine the peculiarities of the action of drugs in a person; a knowledge of the most clinically significant genetic polymorphisms that affect the effectiveness and toxicity of pharmacotherapy; a knowledge of predicting the action of drugs in a person according to his/her genetic characteristics, to be able to use available literature data / databases, as well as adjust a dose of the drugs.

**Expected results:**

As a result of studying of the elected course, students should know:

- Factors that affect the drugs' absorption, distribution, biotransformation and excretion from the body;
- Factors that determine drugs' effects;
- Genetic factors of the patient that affect the effectiveness and safety of the drugs;
- Requirements and indications for pharmacogenetic tests;
- Indications for pharmacogenetic testing;
- Interpretation of the results of pharmacogenetic testing and possible changes in the mode of drug administration in accordance with the results of pharmacogenetic testing.

**To be able:**

- to predict an alteration of the drugs' pharmacokinetics depending on genetic polymorphism of the patients;
- to evaluate the results of pharmacogenetic tests;
- to choose the dosage regimen of the drugs or to provide the replacement of drugs depending on the test results;
- to use the primary sources and electronic databases, which provide information on known genetic polymorphisms.

## DISCIPLINE DESCRIPTION

**Forms and methods of teaching**

The course will be presented in the form of seminar classes (30 hours), organization of independent work of students (60 hours).

The following teaching methods are used in teaching of the discipline: explanations, multimedia presentations, situational studying, simulational studying, oral interviews, testing, individual tasks, self-preparation work with the textbook.

**The content of the discipline**

Topic 1. The establishment and development of pharmacogenetics. The basis of individual human sensitivity to the drugs.
Topic 2. The characteristics of pharmacogenetic tests - their informativeness, interpretation of results, and practical application.
Topic 3. Pharmacokinetics of the drugs in the human body. Absorption and distribution of the drugs.
Topic 4. Drugs' biotransformation in the human body.
Topic 5. The enzymes of the drugs' metabolism.
Topic 6. The basics of the drugs' pharmacodynamics.
Topic 7. Pharmacogenetics of the drugs that affect hemostasis.
Topic 8. Pharmacogenetics of the drugs that regulate the function of the cardiovascular system (beta-blockers, statins, etc.)..
Topic 9. Pharmacogenetics of the psychotropic drugs.
Topic 10. Pharmacogenetic features that determine the sensitivity to anticonvulsants and analgesics.
Topic 11. Pharmacogenetic features that determine the sensitivity anticancer and antimicrobial drugs.
Topic 12. Adverse reactions that depend on genetic polymorphism.
Topic 13. Checkup of practical skills and theoretical knowledges. Final class.
Final control of the studied course.

**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. Pharmacogenomics: Challenges and Opportunities in Therapeutic Implementation / Yui-Wing Francis Lam, Stuart R. Scott. - Academic Press, 2018. - 442 p.

4. Betram G Katzung Basic and Clinical Pharmacology, 14th Edition. - McGraw-Hill Medical, 2018.- 1235.

5. Human pharmacogenetic pecularities affecting the action of anti-tuberculosis medicines [Текст] / P. B. Antonenko [et al.] // Клініч. фармація. - 2016. - Том 20, № 1. - С. 6-11 DOI: https://doi.org/10.24959/cphj.16.1374

**Electronic information resources:**

1. http://moz.gov.ua

2. "State Register of Medicines of Ukraine" - Access mode: https://moz.gov.ua/derzhavnij-reestr-likarskih-zasobiv-ukraini

3. ATC-classification - Access mode: https://compendium.com.ua/uk/atc/

4. Online platform with protocols based on evidence-based medicine - Access mode: http://guidelines.moz.gov.ua/

5. Emergency medical care: pre-hospital stage. New clinical protocol / Order of the Ministry of Health of Ukraine 05.06.2019 No 1269 - Access mode: https://moz.gov.ua/uploads/2/12737-dn_20190605_1269_dod.pdf

6. State form of medicines 12th issue, 2020: - Access mode: https://www.dec.gov.ua/materials/chinnij-vipusk-derzhavnogo-formulyara-likarskih-zasobiv/

7. State Expert Center of the Ministry of Health of Ukraine http: // https://www.dec.gov.ua/

8. State Enterprise "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines" http://sphu.org/

9. National Scientific Medical Library of Ukraine http://library.gov.ua/

10. National Library of Ukraine named after VI Vernadsky http://www.nbuv.gov.ua/

11. Resource for predicting drug interactions (based on FDA instructions, in English) URL: http://www.drugs.com

## EVALUATION

**Forms and methods of current control**

Forms of control and the evaluation system are carried out in accordance with the requirements of the standard program of the discipline and the Instruction on the evaluation system of students' educational activities.

Methods of control: oral survey, testing, assessment of performance of practical skills, solving pharmacotherapeutic problems, assessment of activity in class.

**Final control**: final control

Forms of control and the evaluation system are carried out in accordance with the requirements of the standard program of the discipline and the Instruction on the evaluation system of students' educational activities.

**Evaluation of the current educational activity in a practical session:**

1. Evaluation of theoretical knowledge on the subject of the lesson:
   - methods: survey, solving the situational pharmacodynamic problem
   - maximal score – 5, minimal score – 3, failure – 2.
2. Оцінка практичних навичок з теми заняття:
   - methods: assessment of the correctness of practical skills
   - maximal score – 5, minimal score – 3, failure – 2.

**Current evaluation criteria in practical training:**

| Score | Evaluation criteria |
|---|---|
| «5» | The student knows the program in its entirety, illustrating the answers with various examples; gives exhaustively accurate and clear answers without any leading questions; teaches the material without errors and inaccuracies; performs practical tasks of varying degrees of complexity (knows the pharmacology of a drug or drug group thoroughly and is able to write a prescription within the scope of a situational task); |
| «4» | The student knows the entire program and understands it well, answers the questions correctly, consistently and systematically, but they are not exhaustive, although the student answers additional questions without mistakes; performs practical tasks, experiencing difficulties only in the most difficult cases (orients himself within the limits of the above-mentioned issues); |
| «3» | It is given to the student on the basis of his knowledge of the entire scope of the program on the subject and a satisfactory level of understanding of it. The student is able to solve simplified tasks with the help of leading questions; performs practical skills, experiencing difficulties in simple cases; is not able to give an answer systematically on his own, but answers correctly to directly asked questions (has a superficial idea of the drug). |
| «2» | The student does not know the material, does not know any of the above questions, or knows less than 50% of the questions and does not know how to write a prescription. |

***Final control*** - the study of the academic discipline ends with a final lesson. Credit ("pass") is given to students who have not missed seminar classes or completed missed classroom classes and have an average grade of at least 3.0.

**Distribution of points received by higher education applicants**

The average score for the academic discipline is converted into a traditional grade from the discipline on a 4-point scale and is calculated as the ratio of this arithmetic average to the percentage of assimilation of the required amount of knowledge in the subject.

| Average score for the discipline | The ratio of the obtained average score to the maximum possible value | Discipline assessment on a 4-point scale (national) |
|---|---|---|
| 4.45- 5.00 | 90-100 % | 5 |
| 3.74- 4.44 | 75-89 % | 4 |
| 3.00- 3.74 | 60-74 % | 3 |

The traditional assessment of the academic discipline is converted into an assessment on a 200-point scale and further ranked according to the rating scale (ECTS).

## SELF-PREPARATION OF THE STUDENTS

Topics of independent work classes are presented in the work program and the thematic plan of independent work of students of the department. For preparation, students are recommended to use the educational and methodical manual for independent work of medical faculty students in pharmacology and textbooks from the list of recommended literature.

The control of self-preparation of the students, which is provided by the topic along with the classroom work, is carried out during the current control of the topic in the relevant classroom. Topics that are submitted only for independent work and are not included in the topics of classroom training, are controlled during the final control.

## TOPICS OF SELF-PREPARATION CLASSIS (SPC)

1. The emergence and development of pharmacogenetics. The basics of individual sensitivity of a person to the action of drugs.
2. Genetic differences in drug receptors. Clinical significance of pharmacodynamic gene polymorphisms.
3. Types of methods for determining genetic polymorphism.
4. Genetic factors determining the activity of drug biotransformation stages.
5. Pharmacology of drugs affecting the blood coagulation system. Gene polymorphism, which determines the features of the action of anticoagulants, antiaggregants and their clinical significance.
6. Adverse reactions of drugs affecting leukopoiesis and blood coagulation. Methods of their prevention.
7. Pharmacology of drugs affecting the renin-angiotensin system. Gene polymorphism, which determines the features of the action of ACE inhibitors and their clinical significance
8. Pharmacology of beta-blockers. Gene polymorphism affecting the pharmacokinetics and pharmacodynamics of beta-blockers.
9. Pharmacology of statins. Gene polymorphism affecting the pharmacokinetics and pharmacodynamics of statins.
10. Pharmacology of neuroleptics and antidepressants. Gene polymorphism affecting the pharmacokinetics and pharmacodynamics of antipsychotics and antidepressants.
11. Pharmacology of analgesics. Gene polymorphism affecting the pharmacokinetics and pharmacodynamics of analgesics.
12. Pharmacology of anticancer agents. Gene polymorphism affecting the pharmacokinetics and pharmacodynamics of anticancer drugs.
13. Pharmacogenetic factor in the occurrence of side effects of drugs.
14. Pharmacology of antimicrobial agents. Gene polymorphism affecting the pharmacokinetics and pharmacodynamics of anticancer drugs.

## COURSE POLICY

**Deadline and recompilation policy**

Timely completion of the tasks set by the teacher in a timely manner is mandatory. For late performance of the task during the current / final control of knowledge the student receives an unsatisfactory grade. Reassignment is carried out according to the approved schedule with the permission of the dean's office.

**A policy of academic integrity**

Adherence to academic integrity by students involves:

- independent performance of all types of work, tasks, 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.

Write-off and plagiarism are not allowed.

**Attendance and lateness policy**

Attendance at lectures and practical classes is mandatory, exceptions are possible only if an individual study schedule is approved for an individual student. Late classes are not allowed. The omission of classes, regardless of the reason for the omission, the student of higher education works for the teacher in accordance with the schedule of consultations and practice of missed classes.

**Mobile devices**

The use of a mobile phone, tablet or other mobile devices during the lesson is not allowed (except in cases provided by the curriculum and guidelines of the teacher).

**Behavior in the audience**

Keeping quiet among students in lectures, exceptions - students' questions to the teacher regarding the explanation of the material; working discussion atmosphere in practical classes during the survey; adherence to the ethics of academic relations.

Authors:
Ph.D., Senior teacher, professor Antonenko K.O.

Doctor of Medical Sciences,
Professor Antonenko P.B.

Head of the Department,
Doctor of Medical Sciences,
Professor Rozhkovsky Ya.V.