


National Pirogov Memorial Medical University, Vinnytsya


«APPROVE»

Acting rector of higher education institution


Viktoriia PETRUSHENKO
"31" "08" 2023

«AGREED»

Head of clinical pharmacy and
clinical pharmacology department


Sviatoslav SEMENENKO
"31" "08" 2023

**SYLLABUS
of academic discipline**

SIDE EFFECT OF DRUGS

Specialty	222 Medicine
Educational level	the second (master's) level
Educational programme	EPP Medicine, 2022
Academic year	2023-2024
Department	<i>Clinical pharmacy and clinical pharmacology</i>
Lecturer	Ass-prof. Inna Doroshkevych, Prof. Kateryna Pivtorak
Contact information	<i>clinpharm@vnm.edu.ua, Pirogov str, 56</i>
Syllabus compiler	Ass-prof. Inna Doroshkevych

1. Status and structure of the discipline

Discipline status	Optional
Discipline code in EPP/discipline place in EPP	VK 4.2, optional component of professional training
Course / semester	4-th year (VII semesters)
The amount of discipline (the total number of hours / number of credits ECTS)	60 hours / 2,0 credit ECTS
Number of content modules	1 module
The structure of the discipline	Lectures - 14 hours Practical classes 16 hours Independent work 30 hours In general: auditory classes – 50%, independent work - 50%
Language of study	English
Form of study	Full-time (<i>or remote full-time by order</i>)

2. Description of the discipline

Short annotation of the course, relevance.

The program for the study of the academic discipline "Side Effects of Drugs" is compiled in accordance with the procedure for training applicants of the second (master's) level of education in higher medical educational institutions of Ukraine in accordance with the requirements of the ECTS credit transfer system of the organization of the educational process, the exemplary curriculum for the training of specialists of the second (master's) level level of higher education in the field of knowledge 22 "Health care" specialty "Medicine".

The discipline is a mandatory component of the educational and professional program "Medicine", the cycle of professional training of the Master of Medicine, calculated for 2.0 credits, which students acquire during the VII semester of the 4th year of study.

The main focus of the program is the acquisition of knowledge in the discipline "Side effects of drugs", the study of which is necessary for the successful assimilation of the disciplines of professional training. The subject area of the program is the study of mechanisms of occurrence, manifestations, symptoms of overdose and prevention of adverse drug reactions, taking into account their group affiliation, features of pharmacokinetics, pharmacodynamics, main indications for prescribing and interaction with other drugs. The program is focused on the formation of skills for developing a strategy and tactics for the treatment of the disease in a specific patient, taking into account the possible risks of side effects of drugs against the background of comorbidity of the pathology, and to carry out dynamic control of the effectiveness and safety of drug therapy.

The main task in teaching the subject should be the preparation of a specialist with a sufficient amount of theoretical knowledge and practical skills to carry out the most rational drug therapy for a specific patient, who possesses the methodology of individual selection of effective and safe drugs on the basis of pharmacokinetics, pharmacodynamics, possible manifestations of side effects, features of the course of the disease, age of the patient, accompanying pathology, optimal dosage forms, formulation of rational drug combinations.

Prerequisites. For successful mastering of discipline, the student needs the knowledge received in the course of studying of the following disciplines of the general preparation: latin, ethics, philosophy,

ecology, medical biology, medical chemistry, biological and bioorganic chemistry, biophysics, human anatomy, pathological anatomy, physiology, pathological physiology, microbiology, pharmacology.

The purpose of the optional educational discipline "Side Effects of Drugs" involves the acquisition by each student of theoretical knowledge and practical skills regarding the basic principles of substantiation of the rational and safe for human health use of medicinal products, taking into account the possible occurrence of adverse reactions. Achieving the goal will allow students to be prepared for practical activities, high-quality performance of functional duties related to the rational choice of drugs, which will contribute to reducing the frequency of adverse reactions to drugs, prevention of polypharmacy and drug-related illness.

Postrequisites. As a training discipline "Side Effects of Drugs" lays the foundations for the formation of ideas and skills to apply the general principles of drug therapy of major diseases, syndromes and their individual manifestations in therapy, surgery, obstetrics, gynecology and anesthesiology.

3. Learning outcomes.

After successful study of the discipline the applicant will be able to:

- Provide pharmacological and pharmacotherapeutic characteristics of medicinal products, logically link the mechanism of action with pharmacodynamics, pharmacodynamics with indications, and side effects with contraindications to their use;
- To determine, depending on the features of the pharmacokinetics of medicinal products, the frequency of taking the medicinal product, its daily, course dose in patients of different ages in accordance with concomitant diseases and the use of other medicinal products;
- To predict the consequences of the interaction of drugs when they are combined, drugs and food components, drugs and alcohol;
- Assess the benefit/risk ratio when using medicines;
- Make judgments about the possibility of side effects of medicinal products in order to prevent them;
- predict the risk of side effects of drugs; determine the manifestations of possible adverse drug reactions, symptoms of overdose with potent and poisonous drugs, methods of their prevention and principles of treatment;
- Create an algorithm for helping patients with acute drug poisoning with the use of antidotes in each specific case;
- Provide comparative characteristics of medicinal products based on indicators of effectiveness, safety, mechanism of action, indications for use, etc.;
- Choose the necessary set of monitoring methods to assess the pharmacodynamic effects of drugs and interpret the data obtained or choose methods of adequate control over the effectiveness and safety of treatment;
- Fill out the notification card about side effects of medicines.

4. Content and logistic of the discipline

<i>Content module 1. Side Effects of Drugs</i>	VII semester 60 h	Lecture № 1-7 Practical class № 1-8 ISWN № 1-8
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The course includes 8 topics, 1 thematic modules.

Content module 1. Side Effects of Drugs

Topic 1-2. Side effects of drugs, definitions. Pharmacological supervision in Europe. The influence of pharmacokinetics and pharmacodynamics on drug toxicity. Drug-drug interaction. Methods of monitoring the development of side effects of drugs. Features of the prevention of side effects of drugs. Doctor's tactics at the development of side effects of drugs. Predictors of side effects of drugs depending on age, at pregnancy and lactation. Peculiarities of drug dosage in children and the elderly.

Topic 3. Nephrotoxicity of drugs. Mechanisms of development of adverse reactions from kidneys. The rate of glomerular filtration and its value for calculating the dose of drugs.

Topic 4. Hepatotoxicity of drugs. Mechanisms of toxic effect of drugs on the liver, monitoring of hepatotoxicity of certain groups of drugs, treatment tactics. The concept of hepatoprotectors: classification, features of pharmacodynamics and pharmacokinetics, indications, side effects, contraindications.

Topic 5. Cardiotoxicity of drugs. Side effect of anticoagulants, antiplatelets and thrombolytics.

Topic 6. Hematotoxicity of drugs. Features of drugs usage that can cause disorders of the blood system. Tactics of treatment of hematotoxic reactions caused by drugs.

Topic 7. Neurotoxicity of drugs. Side effect of narcotic analgesics, tranquilizers, sleeping pills, antidepressants.

Topic 8. Drug allergy. Mechanisms of hypersensitivity reactions to drugs. Diagnosis, clinical features and medical treatment of allergy.

The lecture course discovers the problematic issues of the relevant sections of clinical pharmacology. Practical classes provide a theoretical justification of the main issues of the topic and the acquisition of the following practical skills:

- 1) providing pharmacological and pharmacotherapeutic characteristics of medicinal products, logically linking the mechanism of action with pharmacodynamics, pharmacodynamics with indications, and side effects with contraindications to their use;
- 2) determination, depending on the characteristics of the pharmacokinetics of drugs, the frequency of taking the drug, its daily dose, course dose in patients of different ages according to concomitant diseases and the use of other drugs;
- 3) forecasting the consequences of the interaction of drugs when they are combined, drugs and food components, drugs and alcohol;
- 4) assessment of the benefit/risk ratio when using medicines;
- 5) predicting the risk of developing a side effect of drugs; determination of manifestations of possible adverse drug reactions, symptoms of overdose with potent and poisonous drugs, methods of their prevention and principles of treatment;
- 6) creation of an algorithm for helping patients with acute drug poisoning with the use of antidotes in each specific case;

- 7) provision of comparative characteristics of medicinal products based on indicators of effectiveness, safety, mechanism of action, indications for use, etc.;
- 8) filling out the notification card about side effects of medicines.

In practical classes, students solve clinically-oriented situational problems and test tasks.

Independent work of students involves preparation for practical classes and final control. The control of students' independent work is carried out during the current control of the topic in the relevant classroom.

Thematic plans of lectures, calendar plans of practical classes, volume and directions of individual work are published on the website of the department.

The route for obtaining materials: Department of Clinical Pharmacy and Clinical Pharmacology / Student / Full-time / Medicine / 4th year / Educational and methodical materials / or by the link <https://www.vnmu.edu.ua/> Department of Clinical Pharmacy and Clinical Pharmacology #. Access to materials is provided from the student's corporate account s000XXX@vnmu.edu.ua.

5. Forms and methods of monitoring academic performance

Current control in practical studies	Methods: oral or written survey, testing, electronic survey, solving situational problems.
Final control of the discipline - credit	Methods: testing, oral questioning (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmu.edu.ua/General information))
Learning success diagnostic tools	Theoretical questions, tests, clinically-oriented situational tasks.

6. Assessment criteria

Knowledge assessment is carried out in accordance with the Regulations of the Academic process in VNMU named after M.I. Pirogov (link link <https://www.vnmu.edu.ua/General> information)

Continuous assessment	On a four point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Discipline assessments:	Current academic assessment - from 72 to 120 points (conversion of the average traditional assessment of practical class on a 120-point scale): 60% of the grade for the discipline Final control - from 50 to 80 points: 40% of the grade for the discipline Individual work - from 1 to 12 points From 122 to 200 points in total.

Discipline Score Scale: National and ECTS

The sum of grades for all types of educational activities	Score ECTS	Score on a national scale	
		For exam, course project (work), practice	for credit test
180-200	A	excellent	credited
170-179,9	B	good	
160-169,9	C		
141-159,9	D	satisfactory	
122-140,99	E	satisfactory	credited
121-61	FX	unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
1-60	F	unsatisfactory with a mandatory reexamination of discipline	is not credited with mandatory reexamination of discipline

Criteria for student knowledge assessment

Evaluation of the oral / written answer during the current control

The grade **"excellent"** is given to a student who knows the features of the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects, interaction of different groups of drugs. Methods of their appointment, methods for assessing the effectiveness of action, duration of action of drugs. The choice of drugs taking into account the above criteria and the functional state of the body, sex, age of the patient. Rational combinations of therapy. Prevention and measures of immediate therapy in case of complications from treatment. The answers must be deep, meaningful and specific. The student correctly, clearly, logically and fully answers all standardized questions of the current topic, is able to summarize the material.

The grade **"good"** is given to a student who knows the features of the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects, interaction of different groups of drugs. Methods of their appointment, methods of evaluating the effectiveness of action. The choice of drugs taking into account the above criteria and the functional state of the body, sex, age of the patient. Prevention and measures of immediate therapy in case of complications from treatment. The answers are quite meaningful and specific. The student correctly and essentially answers the standardized questions of the current topic. Has the necessary practical skills and abilities in excess of the required minimum.

A grade **"satisfactory"** is given to a student who knows a mandatory minimum of theoretical knowledge and practical skills - to know the representatives of groups of drugs, features of pharmacokinetics, pharmacodynamics, side effects of drugs, methods of administration. The answers are incomplete, the knowledge is superficial.

The grade **"unsatisfactory"** is given to a student who does not have minimum knowledge of drug toxicology, does not focus on pharmacokinetics, pharmacodynamics, side effects of drugs, the peculiarities of their interaction, methods of monitoring therapy and measures for immediate care in case of complications. The answers are vague, incorrect, or completely absent.

Evaluation of test tasks during the current control

The grade "**excellent**" is given to the student who at carrying out test control is allowed no more than 10% of incorrect answers (volume of correct answers 90-100%).

A grade of "**good**" is given to a student who makes no more than 20% of mistakes during the test (the amount of correct answers is 80-89%).

A grade of "**satisfactory**" is given to a student who makes mistakes in no more than 30% of test tasks (the amount of correct answers is 70.5-79%).

A grade of "**unsatisfactory**" is given to a student who correctly solves less than 70% of the test tasks in a test.

Evaluation of the implementation of situational tasks during the current control

The grade "**excellent**" is given to the student freely solves situational clinically-oriented problems of increased complexity, correctly, clearly, logically and fully answers all components of the problem.

A grade of "**good**" is given to the student who is able to solve light and medium situational clinically-oriented problems, while correctly and essentially answers most questions to the problem, correctly uses theoretical knowledge in solving practical problems.

A grade of "**satisfactory**" when solving situational problems, provides correct answers to only some questions to the problem, or the answers are incomplete.

A grade of "**unsatisfactory**" when solving situational problems, he cannot provide the correct answers to the questions to the problem. The answers are vague, incorrect, or completely absent.

Assessment of independent students work

The calculation of individual points is carried out on the basis of the Regulation of the Academic process in VNMU named after M.I. Pyrogov (link <https://www.vnmua.edu.ua/General> information).

12 points are reserved for the ISW assessment, which are accrued as follows:

12 points - added to the assessment of the discipline for a student who won a prize at the interuniversity competitions in the discipline or a prize at the Ukrainian competition of student research reports or a prize at the interuniversity / international scientific conference with the published work;

11-10 points - are added for prizes at intra-university competitions and student scientific conferences with the published work.

10 points - are added to the assessment of the discipline for participation (if the student participated but did not receive a prize) in interuniversity competitions in the discipline and interuniversity and international scientific student conferences with the published work.

8 points - are added to the assessment of the discipline for participation (if the student participated but did not receive a prize) in intra-university competitions and student scientific conferences with the availability of printed work.

6 points - are added to the assessment of the discipline for the manufacture of drugs at the departments, schemes, tables of multimedia software and videos - taking into account the importance of the work performed.

If the sum of points for ISW exceeds 12, the remaining points by the decision of the cathedral meeting can be added as a bonus points to the score on the final modul control.

Students' independent work on a topic that is included in the thematic plan is assessed during the current control of the topic in the relevant lesson.

7. Policy of discipline / course

The student has the right to receive high-quality educational services, access to contemporary scientific and educational information, qualified tutoring during the study of discipline and mastering practical skills. The policy of the department during the providing of educational services is a student-centered, based on normative documents of the Ministry of Education and the Ministry of Health of Ukraine, the Statute of the University and the Procedure for the Providing of Educational Services regulated by the main principles of the organization of the educational process in VNMU named after M.I.Pirogov and the principles of academic integrity (link <https://www.vnmue.edu.ua/General> information).

Adherence to the rules of VNMU, safety techniques in practical classes.

Safety instruction is given at the first practical session by the teacher.

ALGORITHM OF ACTION for education applicants, scientific and pedagogical workers of National Pirogov Memorial Medical University, Vinnytsia throughout the operation of the «AIR ALARM» during working hours

Before the first class starts, teacher must explain extensively how to get to the shelter.

The shelters of the Department of Clinical Pharmacy and Clinical Pharmacology are located at the ground floor of morphological building of the VNMU, the cellar-shelter of the hostel №3, the basement-shelter of the University Clinic of the VNMU, the basement - shelters of VCCH №.3 in accordance with the base for conducting practical classes.

In case when the alarm signal sounds during the classes «AIR RAID! EVERYONE GOES TO THE NEAREST SHELTER» it is necessary to: Stop the class immediately; after the teacher announces: «Pack your things, quickly go to the shelter», quickly pack things and get ready to leave; make sure that there is no one left in the auditorium; turn off the light, close the door (mainly performed by the teacher); follow the last student to move to the shelter (performed by the teacher); stay at the shelter until the signal «CAUTION! ALL-CLEAR!» (two short sirens announcing same as for the sounding of the air alarm); after the signal «CAUTION! ALL-CLEAR!» return to the classroom to continue the lesson; if the signal «CAUTION! ALL-CLEAR!» do not occur before the end of the class, the education applicants should stay at the shelter until the signal «CAUTION! ALL-CLEAR!»; in case when the alarm signal «AIR RAID! EVERYONE GOES TO THE NEAREST SHELTER» sounds before the start of the class and the applicants arrive to the department base, the applicants must immediately go to the nearest shelter (QR code with a link to the map of the shelters of Vinnytsia city are sited at every public transport stop).

Requirements for preparation for practical classes.

The student must be prepared for a practical lesson, theoretically prepared for the topic.

Student should come to a class on time, without delay. A student who is more than 10 minutes late for class is not allowed to the last and must work it in the prescribed manner.

In practical classes, the student must be dressed in a medical gown.

When discussing theoretical issues, students should demonstrate tolerance, courtesy and respect for their colleagues and the teacher.

Usage of mobile phones and other electronic devices.

The use of mobile phones and other electronic devices during the lesson is allowed only at the instruction of the teacher.

Academic integrity. When studying the discipline, the student must be guided by the Code of Academic Integrity and Corporate Ethics of VNMU named after M.I. Pirogov (link: <https://www.vnmue.edu.ua/General> information)/ Code of Academic Integrity). In case of violation of the norms of academic integrity during the current and final controls student receives a grade of "2"

and must work it out to his teacher in the prescribed manner within two weeks after receiving an unsatisfactory assessment).

Missed classes. Missed classes are working out in the manner prescribed by Regulations of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmu.edu.ua/General> information) at the time of work out schedule (published on the website of the department [https://www.vnmu.edu.ua/ Department of Microbiology #](https://www.vnmu.edu.ua/Department%20of%20Microbiology%20#)) to the teacher on duty. To work out missed lesson student must provide a completed workbook protocol on the relevant topic, take a test and answer questions in writing or orally to the topic of the lesson.

The procedure for admission to the discipline final control is given in the Regulation of the Academic process in VNMU named after M.I. Pyrogov (link <https://www.vnmu.edu.ua/General> information). Students who do not have missed practical classes and lectures and received an average traditional grade of at least "3" are allowed to final control.

Additional points. Individual points in the discipline that student can receive for individual work, is determined by the results of his individual work according to Regulation of the Academic process in VNMU named after M.I. Pyrogov (link <https://www.vnmu.edu.ua/General> information) and policy of the course.

Conflict resolution. In case of misunderstandings and complaints to the teacher because of the quality of educational services, knowledge assessment and other conflict situations, student should submit his / her claims to the teacher. If the issue is not resolved, the student has a right to apply to the head of the department according to Complaints Consideration Procedure ([https://www.vnmu.edu.ua/ General information / Basic documents](https://www.vnmu.edu.ua/General%20information/Basic%20documents)).

Politics in terms of remote learning. Distance learning regulated by the Regulations of the elements of remote learning in VNMU named after Pirogov M.I. ([https://www.vnmu.edu.ua/ General information](https://www.vnmu.edu.ua/General%20information)). The main training platforms for studying are Microsoft Team and Google Meets. Practical classes and lectures, exercises and consultations during distance learning is published on the website of the department ([https://www.vnmu.edu.ua/ Department of Clinical Pharmacy and Clinical Pharmacology/Student](https://www.vnmu.edu.ua/Department%20of%20Clinical%20Pharmacy%20and%20Clinical%20Pharmacology/Student) or [https://www.vnmu.edu.ua/Department of of Clinical Pharmacy and Clinical Pharmacology / News](https://www.vnmu.edu.ua/Department%20of%20Clinical%20Pharmacy%20and%20Clinical%20Pharmacology/News)).

Feedback from teachers is via messengers, e-mail or on the Microsoft Teams platform (at the choice of the teacher) during working hours.

8. Educational resources.

Educational and methodological support of the discipline is published on the website of the department ([https://www.vnmu.edu.ua/ Department of Clinical Pharmacy and Clinical Pharmacology/ To students](https://www.vnmu.edu.ua/Department%20of%20Clinical%20Pharmacy%20and%20Clinical%20Pharmacology/To%20students)).

Recommended base reading:

1. V. Bobyrov. Pharmacology: textbook / V.Bobyrov, T.Devyatkina, O.Vazhnicha, V.Khristyuk. - 3rd ml ., updated - Vinnitsya : Nova Knyha, 2015. -520 p.: il.
2. Brunton L.L., Chabner B.A., Knollmann B.C. Goodman and Gilman's The Pharmacological Basis of Therapeutics (12-th Edition).-2010.
3. Essentials of medical pharmacology / edited by Tripathi KD. - 6th edition. – New Delhi, 2010. – 940 p.
4. Handbook of Drug Interactions: a clinical and forensic guide. - Edited by A. Mozayani, H. County, L.P. Raymon -2004.-662 p.

5. H. Lüllmann, A. Ziegler et al. Color Atlas of Pharmacology.-2000.-662 p.
6. Katzung B.G., Masters S.B., Trevor A.J. Basic & Clinical Pharmacology (14-th Edition).- 2018.- 1547 p.
7. Pharmacology - Cito!: Textbook II Edited by S.M. Drogozov. - Kharkiv, 2016. -192 p.
8. Pharmacology at your palms: reference book / Drogozov S.M., Kutsenko T.A. - Kharkiv: Nphall, 2016.-80 p.
9. Pharmacology / [edited by] Karen Whalen ; collaborating editors, Richard Finkel, Thomas A. Panavelil. – Sixth edition. – 2015. (Lippincott illustrated reviews)
10. Rational use of medicines: progress in implementing the WHO medicines strategy Report by the Secretariat, EB118/6, 11 May 2006, [Електронний ресурс].–Режим доступу: who.int/gb/ebwha/pdf_files/EB118/B118_6-en.pdf
11. Websites PubMed, MEDLINE, MD Consult, UptoDate, Clinical Evidence etc.
12. The European Association for Clinical Pharmacology and Therapeutics (EACPT) <http://www.eacpt.org>
13. Drug interactions resource: <http://medicine.iupui.edu/flockart/>

Recommended additional reading:

1. Pharmacology at your palms: reference book / Drogozov S.M., Kutsenko T.A. - Kharkiv: Nphall, 2016, 80 p.

Electronic resources:

1. Deartment website – <http://vnmu.edu.ua/>
2. Libraire website - <http://library.vsmu.edu.ua/>
3. State Register of Medicines www.moz.gov.ua
4. Unified patient management protocols www.moz.gov.ua
5. Australian Bulletin of Adverse Reactions.<http://www.tga.health.gov.au/adr/aadrb.htm>.
6. British Monthly Drug Safety Bulletin <http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>.
7. Lectures for postgraduate education "Principles of Clinical Pharmacology" of the Clinical Center of the National Institutes of Health. <http://www.cc.nih.gov/researchers/training/principles.shtml>.
8. Interregional Society of Evidence-Based Medicine: <http://www.osdm.org/index.php>
9. Bulletin of evidence-based medicine: <http://www.evidence-update.ru>
10. European Society of Clinical Pharmacologists and Pharmacotherapists: <http://www.eacpt.org>
11. Resource on pharmacogenetics. <http://www.pharmgkb.org/>.
12. On-line registration of adverse drug reactions on the FDA website. <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.
13. Resource for drug interaction: <http://medicine.iupui.edu/flockart/>
14. Working group on pharmacotherapy of the European Society of Cardiology <https://www.escardio.org/>.

Consultations are held twice a week according to the consultation schedule.

9. The timetable and distribution of groups with assigned teachers are published on the web page of the department (<https://www.vnmu.edu.ua/> Clinical pharmacy and clinical pharmacology department/ For students).

The syllabus of the discipline «Side effects of drugs» was discussed and approved at the meeting of the clinical pharmacy and clinical pharmacology department (record № 1, dated 28.08.2023)

Responsible for academic discipline  ass. prof. of HEI Inna DOROSHKEVYCH

Acting head of the department  ass. prof. of HEI Sviatoslav SEMENENKO