Ministry of Healthcare of Ukraine
Poltava State Medical University

Department of internal Medicine № 2

SYLLABUS

INTERNAL MEDICINE (INCLUDING CLINICAL PHARMACOLOGY, CLINICAL IMMUNOLOGY AND ALLERGOLOGY, OCCUPATIONAL DISEASES)

Module 3. Clinical Pharmacology

normative

academic and professional level	the second (master's) level of higher education
field of knowledge	22 «Healthcare»
specialty	222 «Medicine»
academic qualification	Master of Medicine
professional qualification	Doctor
academic and professional program	«Medicine»
mode of study	daily
course(s) and semester(s) of study of the discipline	Module 3. Clinical pharmacology: 5 course 9 semester Module 4. Clinical immunology and allergology: 5 course 10 semester

Poltava – 2023

INFORMATION ABOUT LECTURERS WHO DELIVER THE ACADEMIC DISCIPLINE

Surname, name, patronymic of the lecturer (lecturers), scientific degree, academic title	Vahnenko Andriy V.,PhD, Associate Professor
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MAIN CHARACTERISTICS
of Module 3. Clinical pharmacology

The scope of the academic discipline
Credits number/hours 1,0 / 30 of which:
Practical (hours) – 20
Self-work (hours) – 10
Type of control – final module control

The policy of the academic discipline
The Department pharmacology clinical pharmacology and pharmacy in studying the discipline adheres to the requirements which are spelled out in the Regulations on academic integrity of higher education seekers and employees of the Poltava State Medical University.

General requirements for higher education seekers include: attending classes (inadmissibility of absences, delays); rules of conduct in pharmacology classes (active participation in the topic, culture of behavior); rules of preparation for practical classes (solving test tasks and situational tasks on the topic of the lesson).

The policy of the department is guided by the provisions of the Ukrainian legislation " About Education", "About Higher Education", the Statute of PSMU and the following Regulations:

Regulation on the organization of the educational process at Poltava State Medical University.

Internal code of conduct for students of Poltava State Medical University.

Regulation on the organization and methods for assessment of educational activities of higher education recipients at Poltava State Medical University.

Regulation on the organization of self-directed work of students at Poltava State Medical University.

The above Regulations can be found in detail at the link
https://www.pdmu.edu.ua/n-process/department-npr/normativni-dokumenti

Description
Module 3. Clinical pharmacology

The introduction of a large number of medicines into clinical practice and the need to determine their efficacy and safety necessitates a unique approach to the system of studying their pharmacokinetics, pharmacodynamics, interactions and adverse effects in patients. This was the reason for the introduction of a new medical discipline - Clinical Pharmacology - into the training curriculum of doctors in the late 60s and early 70s of the twentieth century.

Clinical pharmacology is the science concerned with the study of pharmaceutical products in their use on humans. It teaches the doctor to select the most effective and safest drug for individualised therapy and prevention, taking into account the underlying medical conditions. Deeper knowledge of

clinical pharmacology will allow to choose the correct treatment regimen, drug forms and ways of administration, to prevent and eliminate side effects and inappropriate interactions between drugs.

The subject of study

Module 3. Clinical pharmacology is an effect of drugs on the body of patient, clinical pharmacokinetics and pharmacodynamics of drugs, methods of monitoring the effectiveness and safety of drugs.

Prerequisites and postrequisites of the discipline (interdisciplinary links)

Prerequisites

Study of Module 3. Clinical pharmacology are based on the knowledge gained by students in the study of such disciplines as: Ukrainian language (for professional purposes). Philosophy. Latin language and medical terminology. Medical biology. Medical and biological physics. Medical chemistry. Biological and bioorganic chemistry. Human anatomy. Histology, cytology and embryology. Foreign language (for professional purposes). Physiology. Microbiology, virology and immunology. Propaedeutics of internal medicine. Hygiene and ecology. Pathomorphology. Pathophysiology. Pharmacology. Pediatrics. General surgery.

Postrequisites

Module 3. Clinical pharmacology lays the foundations for further study by students of such disciplines as: Phthisiology. Ophthalmology. Psychiatry and narcology. Obstetrics. Pediatrics. Surgery. Infectious diseases. Neurology. Otorhinolaryngology. Oncology and radiation medicine. Emergency and urgent medical care. Social medicine, public health. Hygiene and ecology. Training of officers in the field of knowledge "Health".

The Purpose and objectives of:

- *the purpose of the study*

Module 3. Clinical Pharmacology is to prepare specialists with a sufficient amount of theoretical knowledge and practical skills for conducting the most rational drug therapy for a particular patient, owning the methodology for choosing the most effective and safe drugs, as well as their combinations, taking into account the individual characteristics of the body, the course and form of the disease, the presence of concomitant pathology, based on evidence-based medicine

- *the main objectives of the study*

Module 3. Clinical Pharmacology is the training of a specialist with a sufficient amount of theoretical knowledge and practical skills for conducting the most rational drug therapy in a particular patient, who has a methodology for individual selection of effective and safe drugs based on pharmacokinetics, pharmacodynamics, possible manifestations of side effects, the course of the disease, patient age, optimal dosage forms making rational drug combinations.

Competencies and learning results , formation of which is facilitated by discipline (integral, general, special)

Module 3. Clinical pharmacology

- integral:

The ability to solve complex tasks and tasks in the field of health care in the specialty “Dentistry” in a professional activity or in the learning process, provides for research and/or innovation and is characterized by uncertain conditions and requirements.

- general:

1. Ability to abstract thinking, analysis and synthesis, the ability to learn and master modern knowledge.

2. Ability to apply knowledge in practical situations.

3. Knowledge and understanding of the subject area and understanding professional activity.

4. Ability to adapt and act in a new situation.

5. Ability to make informed decisions; work in team; interpersonal skills.

6. Ability to communicate in the state language both orally and in writing; ability to communicate in a foreign language. Ability use international Greco-Latin terms, abbreviations and clichés in professional oral and written speech.

7. Skills in the use of information and communication technologies.

8. Definiteness and persistence in relation to the tasks and responsibilities.

9. The ability to act socially responsibly and consciously.

- *special:*

1. Patient interviewing skills.

2. Ability to determine the required list of laboratory and instrumental studies and evaluate their results.

3. Ability to establish a preliminary and clinical diagnosis of the disease.

4. Ability to determine the required mode of work and rest in the treatment of diseases.

5. Ability to determine the nature of nutrition in the treatment of diseases.

6. Ability to determine the principles and nature of treatment of diseases.

7. Ability to diagnose emergencies.

8. Ability to determine the tactics of emergency medical care.

9. Skills in providing emergency medical care.

10. Ability to carry out medical and evacuation measures.

11. Skills of medical manipulations.

12. Ability to determine the tactics of management of persons subject to dispensary supervision.

13. Ability to conduct working capacity examination

14. Ability to keep medical documentation.

15. Ability to conduct epidemiological and medical-statistical research on the health of the population; processing state, social, economic and health information.

16. Ability to assess the impact of the environment, socio-economic and biological determinants on the health of the individual, family, population.

17. Responsibility to analyse the performance of the doctor, department, health care facility, to take measures to ensure the quality of medical care and to improve the efficiency of the use of medical resources.

18. Ability to take measures to organize and integrate the provision of medical care to the population and the marketing of medical services.

Program learning outcomes, the formation of which is facilitated: Module 3. Clinical pharmacology**:**

1. Knowledge of the structure and function of individual organs and systems and the human body as a whole in the norm, with the development of pathological processes, diseases; be able to use the acquired knowledge in further training and in the practice of the doctor.

2. Collect data on patient complaints, life history (professional history in particular) in a health care facility and/or at the patient's home, according to the standard survey scheme.

3. Assign and analyze additional (mandatory and optional) examination methods (laboratory, radiological, functional and/or instrumental). Evaluate information for the purpose of differential diagnosis of diseases, using knowledge about human, organs and systems, based on the results of laboratory and instrumental studies.

4. Establish a preliminary and clinical diagnosis of the disease on the basis of leading clinical symptoms or syndromes by making an informed decision and logical analysis, using the most probable or syndrome diagnosis, laboratory and instrumental examination of the patient, conclusions of differential diagnosis, knowledge of human, his organs and systems, adhering to the relevant ethical and legal norms.

5. To determine the necessary mode of work and rest in the treatment of the disease in the health care facility, at the patient's home and at the stages of medical evacuation, including in the field, on the basis of a preliminary clinical diagnosis, using knowledge about human, organs and systems, adhering to the relevant ethical and legal norms, by making an informed decision according to existing algorithms and standard schemes.

6. Prescribe the necessary medical nutrition in the treatment of the disease, in a health care facility, at the patient's home and at the stages of medical evacuation, including in the field on the basis of a preliminary clinical diagnosis, using knowledge about human, organs and systems, adhering to the relevant ethical and legal norms, by making an informed decision according to existing algorithms and standard schemes.

7. To determine the character of treatment of the disease (conservative, operative) and its principles in the conditions of the health care institution, at the patient's home and at the stages of medical evacuation, including in the field on the basis of a preliminary clinical diagnosis, using knowledge about human, organs and systems, adhering to the relevant ethical and legal norms, by making an informed decision according to existing algorithms and standard schemes.

8. Carry out diagnostics of emergencies and establish a diagnosis by making an informed decision and assessing the person's condition under any circumstances (at home, on the street, in a health care facility), including in emergency situations, in field conditions, in conditions of lack of information and limited time, using standard methods of physical examination and possible anamnesis, knowledge about human, organs and systems, adhering to the relevant ethical and legal norms.

9. Determine the tactics of emergency medical care, under any circumstances, using knowledge about the human, organs and systems, adhering to the relevant ethical and legal norms, by making an informed decision, based on the diagnosis in a limited time using standard schemes.

10. Provide emergency medical care under any circumstances, using knowledge about human, organs and systems, adhering to the relevant ethical and legal norms, by making an informed decision, based on a diagnosis of emergency for a limited time according to certain tactics, using standard schemes.

11. Perform medical manipulations in a health care facility, at home or at work on the basis of a previous clinical diagnosis and/or indicators of the patient's condition, using knowledge about the human, organs and systems, adhering to relevant ethical and legal norms by making an informed decision and using standard techniques.

12. Determine the tactics of managing persons subject to dispensary observation in a health care institution or at home with a patient based on the data obtained about the patient's health, using standard schemes, using knowledge about a person, his organs and systems, adhering to the relevant ethical and legal standards, by making an informed decision.

13. Carry out examination of working capacity by determining the presence and degrees of disability, type, degree and duration of incapacity with the relevant documents in a health care facility on the basis of data on the disease and its course, features of professional activity.

14. Maintain medical records of the patient and the population on the basis of regulations, using standard technology. Prepare reports on personal production activities, using official accounting documents in the standard form.

15. Adhere to a healthy lifestyle, use the techniques of self-regulation and self-control.

16. To be aware of and guided in their activities by civil rights, freedoms and responsibilities, to constantly improve their professional and cultural levels.

17. Adhere to the requirements of ethics, bioethics and deontology in their professional activities.

18. To provide the necessary level of individual safety (own and persons cared for) in case of typical dangerous situations in the individual field of activity.

Thematic plan of seminars on modules and content modules indicating the main issues addressed at the seminar (According to the working curriculum - not provided).

Thematic plan of practical classes on modules and content modules with an indication of the main issues addressed in the practical lesson

№	Name of topics	The hours
	Module 3. Clinical Pharmacology	
1.	**Object and the task to clinical pharmacology. The basic condition of pharmacokinetics and pharmacodynamics. Interaction of medicines, the forms of the side-action of medicines, complication of the drug therapy. The clinico-pharmacological characteristic of the medicines, which influence homeostasis and lipid exchange.** The subject, objectives, goals of the study of clinical pharmacology. The basic concepts of discipline. The algorithm for choosing drugs for a particular patient. Routes of administration, distribution, biotransformation, excretion of drugs. The mechanism of action of drugs, their pharmacological effects and changes in the state of body functions in response to the effects of drugs. Types of side effects and toxicity. Methods for monitoring the effectiveness and safety of the use of drugs.	4
2.	**The clinico-pharmacological characteristic of antianginal and antiischemic drugs. The clinico-pharmacological characteristic of antihypertensive drugs.** Etiopathogenetic principles of the treatment of coronary heart disease. Classification of antianginal drugs. Features of the choice and combined use of drugs (organic nitrates, beta-adrenoblockers, calcium channel blockers, sydnonimins). Indications and contraindications. Factors that reduce resistance to drugs in this group. Methods for evaluating the effectiveness and safety of use. Etiopathogenetic principles of treatment of arterial hypertension. Classification of hypertensive drugs. Comparative characteristics of drugs, the choice of drugs. Evaluation of the effectiveness and safety of use. Principles of treatment of hypertension and symptomatic hypertension. Classification of antihypertensive drugs. The rationale for the choice of the drug depending on the stage and degree of arterial hypertension and the type of hemodynamics. Characterization of drugs of the first and second line. Comparative characteristics of drugs, in terms of effectiveness, drug compatibility in various flow patterns and the presence of concomitant pathology. The choice of drug and dosage regimen depending on age, the presence of pregnancy. Evaluation of the effectiveness and safety of use. Principles of treatment of hypertensive crises.	4
3.	**The clinico-pharmacological characteristic of drugs that affect bronchial permeability. The clinico-pharmacological characteristic of antiinflammatory drugs.** Modern views on the etiology and pathogenesis of bronchial obstruction syndrome. Classification of drugs affecting bronchial permaebility . Pharmacokinetics and pharmacodynamics. Features of their combined use. The therapeutic efficacy of beta-2 agonists, M-anticholinergics, methylxanthines. The choice of bronchodilator drugs to relieve an attack of bronchial asthma and systematic treatment of COPD, including taking into account the concomitant pathology. Comparative characteristics of their therapeutic value. Side effects of drugs, advantages and disadvantages of various pharmacological groups. Methods for assessing the effectiveness and safety of therapy, taking into account the degree of bronchial obstruction, viscosity of sputum, the state of central and peripheral hemodynamics. Modern ideas about pathological physiology and pathological anatomy of inflammation. Classification of anti-inflammatory drugs (steroidal and non-steroidal). Modern ideas about the mechanism of action. Comparative	4

	characteristics of the anti-inflammatory effects of drugs. Indications and contraindications for use. Schemes of appointment of GCS. Compatibility of drugs in combination therapy of diseases. Side effects, methods for monitoring the effectiveness and safety of anti-inflammatory drugs.	
4.	**The clinico-pharmacological characteristic of antibacterial drugs.** The principles of modern antibiotic therapy. Classification of antibiotics and other antimicrobial drugs. The role of antibiotics and other chemotherapeutic drugs in infectious and purulent-inflammatory diseases. The choice of antibacterial agents in accordance with the sensitivity of microorganisms and the localization of the process, the severity of the disease. Side effects and contraindications for antibiotic therapy. The choice of antimicrobial drugs depending on the pharmacokinetics. Age features of antibiotic therapy. Antibiotic resistance and ways to overcome it. Clinical pharmacology of imidazole, fluoroquinolones, sulfonamides, nitrofurans.	4
5.	**The clinico-pharmacological characteristic of drugs that affect the functions of the digestive tract, hepatobiliary system and pancreas. Defence of "the Protocol of effectiveness and safety of the use of medicines". Final module control.** Determination of the principles of pharmacotherapy of gastric ulcer and duodenal ulcer, gastritis, colitis, irritable bowel syndrome, gastroesophageal reflux disease. The value of drugs that affect the secretory function of the stomach (proton pump inhibitors, H2-histamine blockers, M-anticholinergics; stimulating secretory function). Helicobacter pylori therapy (drugs, doses, duration). Gastrocytoprotectors. Drug regulation of gastrointestinal motility. Significance of symptomatic agents: antiemetic and emetic, laxatives and antidiarrheal. Modern principles of prevention and treatment of intestinal dysbiosis. Modern principles of treatment of acute and chronic cholecystitis, hepatitis, pancreatitis. The rationale for the selection and characterization of drugs with enzymatic and antifermental properties. Features of the joint use of drugs. Pharmacokinetics and pharmacodynamics of choleretics, cholekinetics, hepatoprotectors, antispasmodics. Indications and contraindications. Side effect. Methods for monitoring the effectiveness and safety of drugs. It includes independent (individual) work-supervision of the patient with the writing of the "Protocol for the efficacy and safety of medicines". Each student receives a form of the "Protocol ...", which he fills out when working with the patient during extracurricular time. Diagnosed. A treatment plan is prescribed. The characteristics of medications intended (substantiation of prescription, safety assessment of drugs taken by the interaction of drugs intended for the patient, recommendations for outpatient treatment) is given. Justification (in oral form) of the choice of rational pharmacotherapy for the treatment of a particular patient: methods and dosage regimens of drugs taking into account pharmacokinetic parameters, selected drug combinations, principles for preventing side effects and methods for monitoring the effectiveness of treatment.	4
Total		20

Individual tasks

Individual tasks in Module 3. Clinical Pharmacology and Module 4. Clinical immunology and allergology is one of the forms of organization of training at the university, which aims to deepen, generalize and consolidate the knowledge that students acquire in the learning process, as well as the use of this knowledge in practice. Individual tasks are performed by students independently under the supervision of the teacher. Task for self-study work includes the examination of topics on clinical pharmacology and clinical immunology and allergology, which are not included in the schedule of practical exercises. Creating and presenting multimedia presentations, writing reports and translating

scientific literature.

Participation in the first stage of the All-Ukrainian Olympiad in clinical pharmacology and clinical immunology and allergology.

The list of theoretical questions for students' preparation for the final module control

Module 3. Clinical Pharmacology

1. Clinical pharmacodynamics, definitions, place and role in the choice of pharmacotherapy.
2. Clinical pharmacokinetics, definitions, basic concepts, role in the choice of pharmacotherapy.
3. Classification of lipid-lowering drugs.
4. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications to the appointment of statins.
5. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications to the appointment of fibrates.
6. Omega-3-polyunsaturated fatty acids. Mechanism of action. Features of the application.
7. Classification of dyslipidemia. A differentiated approach to the use of lipid-lowering drugs.
8. Groups of drugs related to antianginal and antiischemic drugs.
9. Mechanism of action, pharmacological effects, indications and contraindications to the appointment of nitrates.
10. Mechanism of action, pharmacological effects, indications and contraindications to the appointment of beta-blockers.
11. Mechanism of action, pharmacological effects, indications and contraindications to the appointment of calcium channel blockers.
12. Classification of calcium channel blockers. Features of the application. Dosages.
13. Classification of beta-blockers. Features of the application. Dosing.
14. Antiaggregant drugs. Classification. Mechanisms of action. Dosing methods.
15. Thrombolytic agents. Indications and contraindications to thrombolysis. Schemes of appointment.
16. Anticoagulants. Classification. Mechanisms of action. Adverse events.
17. Principles of choosing drugs for the treatment of an attack of angina pectoris, acute myocardial infarction.
18. Classification of antihypertensive drugs.
19. Differentiated approach to the administration of antihypertensive therapy in the presence of comorbid diseases (diabetes mellitus, bronchial asthma, pregnancy, advanced age, pheochromocytoma, etc.).
20. The mechanism of antihypertensive action, side effects in the appointment of blockers of calcium channels. Principles of dosing.
21. The mechanism of antihypertensive action, side effects when prescribing beta-blockers. Principles of dosing.
22. Mechanism of antihypertensive action, pharmacological effects, indications and contraindications, adverse events in the appointment of angiotensin converting enzyme inhibitors. Principles of dosing.
23. The mechanism of antihypertensive action, pharmacological effects, indications and contraindications, adverse events in the appointment of angiotensin II receptor antagonists. Principles of dosing.
24. Principles of combined use of antihypertensive drugs.
25. Differentiated choice of drugs for the treatment of hypertensive crises
26. Classification of antiarrhythmic drugs.
27. Differentiated approach to the appointment of antiarrhythmic drugs.
28. Classification of cardiac glycosides. Principles of dosing. Cardiac and non-cardiac effects of cardiac glycosides. Indications for prescribing.
29. Clinical and ECG signs of cardiac glycoside intoxication. Principles of treatment of cardiac

glycoside intoxication.

30. Differentiated choice of drugs for the treatment of cardiac asthma, pulmonary edema.

31. Non-glycosidic cardiotonics positive inotropic drugs. Indications for prescribing.

32. Classification of diuretics.

33. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and protiposages to the appointment of loop diuretics.

34. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and protiposages before the appointment of thiazide and thiazide-like diuretics. Principles of dosing.

35. Mechanism of action and pharmacological effects of potassium-sparing diuretics. Indications and contraindications for use. Dosage regimen.

36. Differentiated approach to the choice of a diuretic drug in the presence of the presence of concomitant diseases (effect on lipid and carbohydrate metabolism).

37. Classification of drugs, affecting bronchial permeability.

38. Mechanism of action, pharmacokinetics, indications and contraindications to the recognition of shortacting beta-2-agonists. Principles of dosing.

39. Mechanism of action, pharmacokinetics, indications and contraindications to the recognition of long-acting beta-2-agonists. Principles of dosing.

40. Methylxanthines, mechanism of action, pharmacological effects, side effects. Principles of dosing.

41. SCS. Pharmacokinetics and pharmacodynamics. Advantages of using inhaled glucocorticoids. Dosing regimes.

42. Adverse events that occur with long-term use of GCS.

43. Mucolytic drugs. Pharmacokinetics and pharmacodynamics. Dosing regimes.

44. Interaction of medicines. Kinds. Clinical examples.

45. Types of side effects when using medicines.

46. Clinical and pharmacological classification of non-steroidal anti-inflammatory drugs.

47. Mechanism of action, pharmacological effects of non-steroidal anti-inflammatory drugs.

48. Indications and contraindications. Side effects when using non-steroidal anti-inflammatory drugs, their prevention and treatment.

49. Modern principles of the choice of antimicrobial drugs.

50. Adverse effects of antibacterial therapy, their profiles

51. Classification of the spectrum of activity, mechanism of action, clinical features of penicillin. Principles of dosing.

52. Classification of the activity spectrum, mechanism of action, clinical features of cephalosporins. Principles of dosing.

53. The spectrum of activity, mechanism of action, features of the clinical use of carbapenems. Principles of dosing.

54. Classification of the spectrum of activity, mechanism of action, features of the clinical use of aminoglycosides. Principles of dosing.

55. Classification of the spectrum of activity, mechanism of action, clinical features of macrolides. Principles of dosing.

56. Classification of the spectrum of activity, mechanism of action, clinical features of the use of fluoroquinolones. Principles of dosing.

57. The spectrum of activity, mechanism of action, clinical features of the use of glycopeptides. Principles of dosing.

58. The spectrum of activity, mechanism of action, clinical features of the use of nitroimidazoles and nitrofurans. Principles of dosing.

59. Clinical and pharmacological characteristics of drugs that stimulate the motor function of the gastrointestinal tract. Principles of dosing.

60. Clinical and pharmacological characteristics of drugs that inhibit the motor-evacuation function of the gastrointestinal tract. Principles of dosing.

61. Medicines with antispasmodic activity, mechanisms of action, pharmacological properties, indications and contraindications for use, principles of use.

62. Classification of drugs with antisecretory activity.

63. Clinical and pharmacological characteristics of proton pump inhibitors. Principles of dosing.

64. Clinical and pharmacological characteristics of H2-receptor blockers. Principles of dosing.

65. Clinical and pharmacological M-anticholinergic. Principles of dosing.

66. Antacids. Classification, pharmacokinetics and pharmacodynamics. Principles of clinical use and dosage.

67. Gastrocytoprotectors. Classification, pharmacokinetics and pharmacodynamics, dosage principles.

68. Hepatoprotectors. Classification. Pharmacokinetics and pharmacodynamics. Indications and contraindications. Principles of dosing.

69. Choleretics and cholekinetics. Clinical and pharmacological features. Indications and contraindications. Principles of dosing.

70. Polyfermental replacement therapy. Pharmacological features. Indications for use. Side effects Principles of dosing.

71. Anti Fermental agents. Classification. Pharmacological features. Indications for use. Principles of dosing.

72. Classification, mechanism of action, pharmacokinetics, indications and contraindications for use, side effects of antiallergic drugs. Principles of dosing.

The list of practical skills for the final module control

Module 3. Clinical Pharmacology

1. To be able to choose the necessary medicines, an adequate dosage form and dosage dosing regimen when prescribed to patients with major pathological syndromes.

2. To determine the main methods of clinical research of patients to assess the effectiveness and safety of prescribing, to analyze their results.

3. Use the basic parameters of pharmacokinetics in order to rationally prescribe drugs.

4.To interpret and take into account in clinical practice the features of clinical pharmacokinetics, pharmacodynamics, side effects and the interaction of the main groups of drugs.

5. Anticipate the effects of drug interactions in combined use, have the skills to prevent and correct the undesirable effects of drugs.

6. Conduct a survey of patients with the aim of collecting a medical history and provide for the possibility of complications of pharmacotherapy.

The form of final control of learning success - <u>final modular control.</u>

System of current and final control

When assessing the mastery of each topic of the module, the student is graded on a 5-point (traditional) scale using developed taking into account the standardized generalized criteria for assessing students' knowledge for the discipline. This takes into account all types of work provided by the guidelines for the study of topics.

Table 1. Standardized generalized criteria for assessing the knowledge of higher education students in PSMU

A 4-point scale	Grades in ECTS	Grades criteria
5 (outstanding)	A	Student shows special creative abilities, is able to acquire knowledge independently, finds and processes necessary information, is able to use the acquired knowledge and skills for making decisions in unusual situations, makes convincing answers, independently reveals own talents and inclinations, possesses not less than 90% of knowledge on the topic both during the survey and all types of control.
4 (good)	B	Student is fluent in the studied amount of material, applies it in practice, freely solves exercises and problems in standardized situations, independently corrects errors, the number of which is insignificant, has at least 85% knowledge of the topic both during asking and all types of control.
	C	Student is able to compare, summarize and systematize information under the guidance of a researcher, independently applies it in practice, to control their own activities; corrects mistakes, chooses arguments to confirm opinions, has at least 75% knowledge of the topic both during asking and all types of control.
3 (pass)	D	Student reproduces a significant part of theoretical material, shows knowledge and understanding of basic provisions with the help of a researcher, can analyze educational material, correct mistakes, has at least 65% knowledge of the topic both during asking and all types of control.
	E	Student has the educational material at a level higher than initial, a significant part of it reproduces at the reproductive level, has at least 60% knowledge of the topic both during asking and all types of control.
2 (insufficient)	FX	Student knows material at the level of individual fragments that make up a small part of the material, has less than 60% knowledge of the topic both during survey and all types of control.
	F	Student knows material at the level of elementary recognition and reproduction of individual facts, elements, has less than 60% knowledge of the topic both during survey and all types of control.

Final Module control (FMC) is carried out at the end of the program material of the module and is held at the last session. To FMC allowed students who scored the required minimum number of points in the course of the final control (the average success score 3.0 or higher), do not have absences from lectures and practical sessions, have mastered the topics assigned for independent work within the module and have fulfilled all the requirements set by the curriculum of the discipline.

The result of the FMC is evaluated in points and is not converted to the traditional 4-point evaluation. The maximum number of FMC scores is 80 points. The minimum number of FMC points for which the control is considered complete is 50 points. The maximum number of points for the module is 200 points (including up to 120 points for the ongoing success).

The conversion of the traditional 5-point scale into a multi-point scale (120 points maximum) - the conversion of the cumulative assessment of the current success for the module - is carried out only after the final lesson, which is followed by the summative assessment. Conversion is carried out according to the following algorithm (Table 2):

- The student's average grade is calculated on a traditional 5-point scale, obtained during the in-progress classes that belong to the given module (with the accuracy to the hundredth point);

- for obtaining a converted multi-point cumulative assessment of the ongoing success for the module the average score received on a traditional 5-point scale must be multiplied by the coefficient of 24. The exception is the case where the average score on a traditional 5-point scale is 2 points. In this case, the student receives 0 points on a point scale;

- the average final success score is based on the total number of sessions in the module, not the actual number of sessions attended by the student.

The minimum converted sum of points of the current success for the module of the discipline is 72 points.

The teaching staff member puts the scores for the module in the "Statement of Final Module Control (as well as the student's individual educational plan).

The student who received a score less than 50 points as a result of composing the FMC is obliged to reschedule the FMC according to the schedule no more than 2 times.

Table 2. Unified table of correspondence of scores for current performance, scores for FMC, exam, and traditional four-point score

Average score for current performance (A)	Points for current success in the module (A * 24)	Points for FMC of the module (A * 16)	Points for the module and/or exam (A * 24 + A * 16)	ECTS category	On a 4-point scale
2	48	32	80	F, FX	2 (unsatisfactory)
2,1	50	34	84		
2,15	52	34	86		
2,2	53	35	88		
2,25	54	36	90		
2,3	55	37	92		
2,35	56	38	94		
2,4	58	38	96		
2,45	59	39	98		
2,5	60	40	100		
2,55	61	41	102		
2,6	62	42	104		
2,65	64	42	106		
2,7	65	43	108		
2,75	66	44	110		
2,8	67	45	112		
2,85	68	46	114		
2,9	70	46	116		
2,95	71	47	118	E	3 (satisfactory)
3	72	50	122		
3,05	73	50	123		
3,1	74	50	124		
3,15	76	50	126		
3,2	77	51	128		
3,25	78	52	130	D	
3,3	79	53	132		
3,35	80	54	134		
3,4	82	54	136		

3,45	83	55	138		
3,5	84	56	140	C	4 (good)
3,55	85	57	142		
3,6	86	58	144		
3,65	88	58	146		
3,7	89	59	148		
3,75	90	60	150		
3,8	91	61	152		
3,85	92	62	154		
3,9	94	62	156		
3,95	95	63	158		
4	96	64	160	B	
4,05	97	65	162		
4,1	98	66	164		
4,15	100	66	166		
4,2	101	67	168		
4,25	102	68	170		
4,3	103	69	172		
4,35	104	70	174		
4,4	106	70	176		
4,45	107	71	178		
4,5	108	72	180	A	5 (excellent)
4,55	109	73	182		
4,6	110	74	184		
4,65	112	74	186		
4,7	113	75	188		
4,75	114	76	190		
4,8	115	77	192		
4,85	116	78	194		
4,9	118	78	196		
4,95	119	79	198		
5	120	80	200		

Control of theoretical and practical training Module 3. Clinical Pharmacology **of the student during the semester final certification is carried out according to the following regulations**:

1. Carrying out of **test control** (within 25 min - performance of 25 selective type test tasks with one correct answer) – **50 points**.

2. Solving two situational problems, followed by prescribing the selected drug (within 10 minutes) – **20 points**.

3. Protection of the "Efficacy and safety protocol of medicines" – **10 points**.

Applicants for higher education, who during the study of the module from which the final control and disciplines had an average score of 4.50 to 5.0 are exempt from the FMC and the exam and automatically (by agreement), receive a final grade in accordance with table 2, while the presence of the applicant at the FMC and the exam is mandatory. In case of disagreement with the assessment, the specified category of applicants for higher education is FMC and exam according to the general rules.

The applicant of higher education has the right to retake the exam no more than 2 times and only during the examination session. The result of the student's exam is recorded in the "Statement of student achievement in the discipline" and sealed with the signatures of the examiner and the head of the department.

Teaching methods

- verbal (lecture, explanation, storytelling, conversation, instruction);
- visual (observation, illustration, demonstration);
- practical (thematic discussions, brainstorming, “round table”, analysis of specific situations (case method), presentations).

Control methods

- oral control;
- written control;
- test control;
- programmable control;
- practical verification;
- self-control;
- self-esteem.

Types of control:

- preliminary (output)
- current;
- final modular control.

Methodological support

1. Working curriculum
2. Syllabus
3. Methodical development of lectures
4. Methodical recommendations for teachers
5. Methodical instructions for independent work of students during preparation for a practical lesson and in class
6. Methodical recommendations on the organization of industrial practice
7. List of recommended reading
8. Materials for control of knowledge, skills and abilities of students:

- tests of different levels of difficulty
- tests from the bank of licensing exams "Step 2"
- situational tasks
- computer control programs

9. Videos.
10. Multimedia presentations.
11. Clinical tests.

Recommended reading

Module 3. Clinical Pharmacology

Basic (available at the library of PSMU):

1. Clinical pharmacology : Manual for practical classes : [навч. посіб. для студентів-іноземців вищ. мед. закладів] / O. B. Крайдашенко, Б. Б. Самура, І. Б. Самура et al. – 3rd ed., updat. – Vinnytsia : Nova Knyha, 2019. – 228 p.
2. Clinical Pharmacology / M. J. Brown, P. Sharma, F. A. Mir, P. N. Bennett. – 12th ed.International ed., IE. – Edinburg etc.: Elsevier, 2019 (China). – 706 p.
3. Parmacolody. Textbook for English-speaking students of higher medical educational institutions / За ред. проф. І.С. Чекмана – V. 4th, updated and redesigned. - Vinnytsia: Nova Knyha, 2018. – 552 с.

Additional:

1. Anthony J. Trevor Basic and Clinical Pharmacology / Anthony J. Trevor, Bertram G. Katzung, Susan B. Masters. - San Francisco : McGraw-Hill Professional. - 2012. - 1248 p.
2. General prescription. Manual for foreign students of pharmaceutical and medical

specialties, teachers, doctors and pharmacists (based on the credit-module system) / [S. Yu. Sthrygol, A. Yu. Pozdniakova, O. V. Tovchiga [et al.]. – Kharkiv: NUPh: Golden Pages, 2012. – 60 p.

3. Michael J. Neal Medical Pharmacology at a Glance / Michael J. Neal. – Willey-Blackwell, 2012. – 115 p.

4. Pharmacology : Manual for practice on special pharmacology / [S. M. Drogovoz, T. A. Kutsenko, A. Yu. Pozdniakova et al.].– Kharkiv: NUPh: Golden Pages, 2012. - 96 p.

Information resources:

1. Basic & Clinical Pharmacology / Edited by Bertram G. Katzung. - San Francisco : McGraw-Hill Professional, 2012. – 1248 p. – Режим доступу: https://www.amazon.com/Basic-Clinical-Pharmacology-Bertram-Katzung/dp/0071825053

Developers:

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Module 3. Clinical Pharmacology

Annex 1

The list of drugs submitted for final control

Calcium channel blockers	
Amlodipine	Tab. 5 and 10 mg
Nifedipine	Tab. 10 mg
Verapamil	Tab. 40 and 80 mg; solution for in. (1 ml - 2.5 mg)
Diltiazem	Tab. 60 and 90 mg
Adrenergic receptor blockers (alpha and beta)	
Bisoprolol	Tab. 5 and 10 mg
Metoprolol	Tab. 50 and 100 mg
Nebivolol	Tab. 5 mg
Carvedilol	Tab. 12.5 and 25 mg
Labalalol	Tab. 100 and 200 mg; sol. for in. (1 ml - 10 mg)
Doxazosin	Tab. 2, 4 and 8 mg
ACE inhibitors	
Captopril	Tab. 25 and 50 mg
Enalapril	Tab. 5, 10 mg; solution for in. (1 ml - 1.25 mg)
Lisinopril	Tab. 10 and 20 mg
Perindopril	Tab. 4 mg
Ramipril	Caps. 2.5 and 5 mg
Angiotensin-II receptor antagonists	
Valsartan	Caps. 80 and 160 mg
Candesartan	Tab. 4, 8 and 16 mg
Losartan	Tab. 50 mg
Telmisartan	Tab. 40 and 80 mg
Combined antihypertensive drugs	
Enalapril / hydrochlorothiazide	Tab. 10/25 mg
Lisinopril / Hydrochlorothiazide	Tab. 10 / 12.5 mg
Lisinopril / Amlodipine	Tab. 10/5 mg
Central sympatholytics	
Alpha-methyldopa	Tab. 250 mg
Clonidine	Tab. 75 and 100 mcg; solution for in. (1 ml - 150 mcg)
Nitrates and Sydnimines	
Isosorbide 5-mononitrate	Tab. 10, 20 and 40 mg
Isosorbide dinitrate	Tab. 20 and 40 mg; sol. for in. (1 ml - 1 mg)
Nitroglycerin	Tab. 500 mcg; solution for in. (1 ml - 5 mg)
Molsidomine	Tab. 2 and 4 mg
F-channel blockers	
Ivabradine	Tab. 5 and 7.5 mg
Antiarrhythmic drugs	
Amiodarone	Tab. 200 mg; solution for in. (1 amp. - 150 mg)
Aethacizinum	Tab. 50 mg
Lidocaine	Sol. for in. (1 ml - 10, 20, 40 or 100 mg)
Propafenone	Tab. 150 and 300 mg; solution for in. (1 ml - 3.5 mg)
Procainamide	Tab. 250 mcg; solution for in. (1 ml - 10 mg)
Totalol	Tab. 80 and 160 mg; solution for in. (1 ml - 10 mg)

Cardiac glycosides and non-glycoside cardiotonic drugs	
Digoxin	Tab. 100 and 250 mcg; solution for in. (1 ml - 125 mcg)
Corgliconum	Sol. for in. (1 ml - 600 mcg)
Dobutamine	Dry substance for in. (1 amp. - 250 mg)
Dopamine	Sol. for in. (1 ml - 5 mg)
Hypolipidemic drugs	
Atorvastatin	Tab. 10 and 20 mg
Rosuvastatin	Tab. 10 and 20 mg
Simvastatin	Tab. 10 and 20 mg
Fenofibrate	Caps. 200 mg
Diuretic drugs	
Hydrochlorothiazide	Tab. 25, 50 and 100 mg
Indapamidunt	Tab. 1.5 and 2.5 mg
Spironolactone	Tab. 25, 50 and 100 mg
Torasemide	Tab. 10, 20, 50 and 100 mg; solution for in. (1 ml - 10 mg)
Furosemide	Tab. 40 mg; sol. for in. (1 ml - 10 mg)
Moduretic	Tab. 5/50 mg
Mannitol	Sol. for i.v. inj. (1 ml-150 mg)
Antiallergic drugs	
Ketotifen	Tab. 1 mg
Cromolin sodium	Caps. 100 mg
Diphenhydramine	Tab. 20 and 50 mg; solution for in. (1 ml - 10 mg)
Clemastine	Tab. 1 mg; solution for in. (1 ml - 1 mg)
Loratadine	Tab. 10 mg
Fexofenadine	Tab. 120 and 180 mg
Chloropyramine	Tab. 25 mg; solution for in. (1 amp. - 20 mg)
Cetirizine	Tab. 10 mg
Drugs that affect bronchial	
Epinephrine	Sol. for in. (1 ml-1 mg)
Ambroxol	Tab. 30 mg; solution for in. (1 ml-7.5 mg)
Acetylcysteine	Tab. 100 mg; solution for in. (1 ml - 100 mg)
Euphyllin	Tab. 150 mg; solution for iv in (1 ml - 24 mg)
Salbutamol	Tab. 2, 4 and 8 mg); Dose aerosol for inhalation (1 dose - 100 mcg)
Salmeterol	Dose aerosol for inhalation (1 dose-25 mcg)
Fenoterol	Tab. 5 mg; Dose aerosol for inhalation (1 dose - 100 mcg)
Tiotropium bromide	1 powder for in. (1 capsule-18 mcg)
Beclometasone	Dose aerosol for in. (1 dose - 50, 100 mcg)
Fluticasone	Dose aerosol for inhalation (1 dose - 25, 50, 125 mcg)
Montelucast	Tab. 5 and 10 mg
Anti-inflammatory drugs	
Hydrocortisone	Suspension for in. (1 vial - 125 mg)
Dexamethasone	Tab. 4 mg; solution for in. (1 ml - 4 mg)
Prednisolone	Tab. 5 mg; solution for in. (1 ml - 30 mg)
Diclofenac sodium	Tab. 50 and 100 mg; solution for in. (1 ml-25 mg)
Meloxicam	Tab. 7.5 and 15 mg
Nimesulide	Tab. 100 mg
Acetaminophen	Tab. 325 and 500 mg
Celecoxib	Caps. 100 and 200 mg
Methylprednisolone	Tab. 4, 16 and 32 mg

Chloroquine	Tab. 250 mg
Antibacterial drugs	
Azithromycin	Tab. 500 mg
Amicacin	Sol. for in. (1 ml - 50, 125 and 250 mg)
Amoxicillin	Tab. 500 mg each; Dry substance for oil in. (1 vial - 500 mg)
Amoxicillin / Clavulanic acid	Tab. 500/125 mg; Dry substance for in. (1 vial - 1000/200 mg)
Benzylpenicillin	Dry substance for in. (1 fl. - 1,000,000 OD)
Vancomycin	Dry substance for in. (1 vial - 500 mg)
Gentamicin	Sol. for in. (1 ml - 40 mg)
Doxycycline	Tab. 100 and 200 mg; Dry substance for in. (1 vial - 10 mg)
Ertapenem	Dry substance for in .. (1 vial-1000 mg)
Imipenem	Dry substance for in. (1 vial-500 mg)
Clarithromycin	Tab. 250 mg; Dry substance for in. (1 vial -500 mg)
Clindamycin	Caps. 150 and 300 mg; solution for in. (1 ml - 150 mg)
Levofloxacin	Tab. 250 and 500 mg
Linezolid	Tab. 400 and 600 mg
Moxifloxacin	Tab. 400 mg
Rifampicin	Tab. 150 and 30 mg
Streptomycin	Powder for in. (1 vial. 1000 mg)
Co-trimoxazolum	Tab. 480 mg
Sulfasalazin	Tab. 500 mg
Tetracycline	Caps. 250 mg
Fluconazole	Caps. 50 and 100 mg
Cefepim	Dry substance for in. (1 vial - 500 and 1000 mg)
Cefotaxime	Dry substance for in. (1 vial - 500 and 1000 mg)
Ceftriaxone	Dry substance for in. (1 vial - 250 and 500 mg)
Cefuroxim	Tab. 250 and 500 mg; Dry substance for in. (1 vial - 750 and 1500 mg)
Ceftazidime	Dry substance for in. (1 vial - 500 and 1000 mg)
Ciprofloxacin	Tab. 500 mg; solution for in. (1 ml -2 mg)
Antiviral drugs	
Aciclovir	Tab. 200, 400 and 800 mg; Dry substance for in. (1 amp. - 250 mg)
Interferon alpha	Sol. for in. (1 ml - 1,000,000, 3,000,000, 6,000,000 MO)
Remantadin	Tab. 50 mg
Ribavirin	Dry substance for inhal. (1 fl. -6 g)
Drugs that affect the functions of the digestive tract	
Atropine sulphate	Sol. for in. (1 ml -1 mg)
Bismuth subcitrate	Tab. 120 mg
Domperidone	Tab. 10 mg
Drotaverine hydrochloride	Tab. 40 mg; solution for in. (1 ml - 20 mg)
Lactulose	Syrup (15 ml - 10 g)
Loperamide	Tab. 2 mg
Metoclopramide	Tab. 5 and 10 mg; solution for in. (1 ml - 5 mg)
Omeprazole	Caps. 20 mg; Dry substance for Ing. (1 vial - 40 mg)
Pantoprazole	Caps. 40 mg
Rabeprazole	Tab. 10 and 20 mg
Pirenzepine	Tab. 25 and 50 mg; solution for in. (1 ml - 5 mg)
Sucralfate	Tab. 1000 mg
Famotidine	Tab. 20 and 40 mg ; dry substance for Ing. (1 vial - 20 mg)

Almagel	Suspension for oral administration (1 ml-100 mg)
Drugs that affect the functions of the digestive system	
Ademetionine	Tab. 400 mg ; dry substance for in. (1 vial - 400 mg)
Essential phospholipids	Caps. 300 mg; 5 ml amp.
Octreotide	Sol. for in. (1 ml - 50 and 100 mcg)
Pancreatin	Caps. 150 and 300 mg
Silymarin	35 mg tablets caps. 70 mg
Ursodeoxycholic acid	Caps. 250 mg
Holagogum	Caps. 40 mg
Drugs affecting the coagulation system	
Alteplase	Dry substance for in. (1 vial - 20 and 50 mg)
Aminocaproic acid	Sol. for in. (1 ml - 50 mg)
Acetytsalicylic acid	Tab. 100 mg
Warfarin	Tab. 2.5 and 3 mg
Vicasolum	Tab. 15 mg; solution for in. (1 ml - 10 mg)
Heparin	Sol. for in. (1 ml - 5000 IU)
Etamsylate	Tab. 250 mg; solution for in. (1 ml - 125 mg)
Enoxaparin sodium	Sol. for in. (1 ml - 100 mg)
Riva roxa ban	Tab. 10 mg
Streptokinase	Dry substance for Ing. (1 fl - 100,000 IU and 250,000 IU)
Clopidogrel	Tab. 75 mg

Annex 2

Study protocol for the efficacy and safety of drug use
(According to the supervision of patients)

Educational research work

Student _____
(full name., Course, group, faculty)
supervisor _____

PROTOCOL
studies of the pharmacodynamics of the drug _____
Patient (name, age, body mass) _____
Clinical diagnosis: underlying disease _____
Complications of the underlying disease _____
Concomitant diseases _____
Study Date: from _____ to _____

1. Patient treatment (provide in the form of prescriptions the 5 most significant drugs, including those selected for a thorough analysis)
2. Justification of the prescription of drugs (international, commercial names, chemical structure, features of the introduction, pharmacokinetics, pharmacodynamics of drugs)
   _____
   _____
   _____
3. Expected therapeutic effect
   _____
   _____
   _____
   _____
4. Possible side effects
   _____
   _____
   _____
   _____
5. List the signs by which the therapeutic efficacy of drugs will be monitored

	Before treatment	After treatment
Subjective		
A)	_____	_____
B)	_____	_____
C)	_____	_____
D)	_____	_____
E)	_____	_____
Physical		
A)	_____	_____
B)	_____	_____
C)	_____	_____
D)	_____	_____

Laboratory and Instrumental

A)_____ _____

B) _____ _____

C)_____ _____

D) _____ _____

6. List the symptoms with which the side effects of drugs will be controlled.

Side effects The presence of a reaction in the patient (yes, no)

Subjective

A)_____ _____

B) _____ _____

C)_____ _____

D) _____ _____

E) _____ _____

Physical

A)_____ _____

B) _____ _____

C)_____ _____

D) _____ _____

Laboratory and Instrumental

A)_____ _____

B) _____ _____

C)_____ _____

D) _____ _____

7. Evaluation of combination therapy (to consider the possibility of co-administration of the drug was evaluated with other drugs from section No. 1: pharmacokinetic, pharmacodynamic, pharmaceutical compatibility) _____
_____

8. Conclusions and recommendations (treatment effectiveness, prognosis of further use, the possibility of replacing other drugs) _____
_____
_____
_____

The study conducted _____ Protocol verified _____

Literature:

Annex 1

Medical history writing scheme

1. Typical 1 page (Department of Experimental and Clinical Pharmacology with Clinical Immunology and Allergology).

2. Passport data: medical history number, age, gender, place of residence, specialty, date of hospitalization. The diagnosis is detailed.

3. Complaints and medical history.

4. Anamnesis of life (indicate the factors that may be the cause of the disease - chronic focal infections, long medication, problems in childhood, etc.).

5. Objective review:

a) general condition - satisfactory, moderate, severe; skin, mucous membranes, peripheral lymph nodes and further according to the scheme;

b) respiratory diseases - according to the standard scheme;

c) diseases of the organs of the cardiovascular system, respectively, according to a typical scheme;

g) diseases of the gastrointestinal tract - according to the standard scheme;

d) kidneys, spleen - according to the standard scheme.

6. Preliminary diagnosis _____:

7. Immunodependent etiopathogenesis.

8. Given the leading clinical syndrome _____

it is necessary to conduct differential diagnosis with: (name two nosological forms). An example for rheumatoid arthritis (RA): periarteritis nodosa, Reiter syndrome.

9. Survey Plan:

a) general clinical examination (do not specify)

b) other laboratory and special immunological studies;

an example for RA: a rheumatoid factor, a variety of vimentin, the level of IgG to chlamydia trachomatis; PCR smear from smear material, etc.

10. Provide data from laboratory tests (including outpatient cards - only pathology).

11. Differential diagnosis.

12. The rationale for the clinical diagnosis.

13. Treatment of the patient during supervision, substantiation of recommendations in terms of immunotropic therapy for the period of inpatient and outpatient treatment. Forecast, labor, medical recommendations.