

MINISTRY OF SCIENCE AND HIGHER EDUCATION OF THE RUSSIAN FEDERATION

**Federal State Autonomous Educational Institution of Higher Education
«National Research Lobachevsky State University of Nizhny Novgorod»**

Институт клинической медицины

УТВЕРЖДЕНО

решением Ученого совета ННГУ

протокол № 10 от 02.12.2024 г.

Working programme of the discipline

Clinical pharmacology

Higher education level

Specialist degree

Area of study / speciality

31.05.01 - General Medicine

Focus /specialization of the study programme

General Medicine

Mode of study

full-time

Nizhny Novgorod

Year of commencement of studies 2025

1. Место дисциплины в структуре ОПОП

Дисциплина Б1.О.50 Клиническая фармакология относится к обязательной части образовательной программы.

2. Планируемые результаты обучения по дисциплине, соотнесенные с планируемыми результатами освоения образовательной программы (компетенциями и индикаторами достижения компетенций)

Формируемые компетенции (код, содержание компетенции)	Планируемые результаты обучения по дисциплине (модулю), в соответствии с индикатором достижения компетенции		Наименование оценочного средства	
	Индикатор достижения компетенции (код, содержание индикатора)	Результаты обучения по дисциплине	Для текущего контроля успеваемости	Для промежуточной аттестации
ОПК-7: Способен назначать лечение и осуществлять контроль его эффективности и безопасности	ОПК-7.1: разрабатывает общий план лечения пациента с учетом этиологии, патогенеза и особенностей течения болезни ОПК-7.2: назначает медикаментозное и немедикаментозное лечение заболеваний и состояний ОПК-7.3: Оценивает эффективность и безопасность медикаментозной и немедикаментозной терапии у взрослых	ОПК-7.1: <i>Develop this overall treatment plan for the patient, taking into account the biology, pathogenesis and course of the disease.</i> ОПК-7.2: <i>Prescribe drug and non-drug treatment for diseases and conditions</i> ОПК-7.3: <i>Evaluates the effectiveness and safety of drug and non-drug therapy in adults.</i>	Задачи Тест Доклад-презентация	Зачёт: Кейс-задание Контрольные вопросы

3. Структура и содержание дисциплины

3.1 Трудоемкость дисциплины

	очная
Общая трудоемкость, з.е.	3
Часов по учебному плану	108
в том числе	
аудиторные занятия (контактная работа):	
- занятия лекционного типа	16
- занятия семинарского типа (практические занятия / лабораторные работы)	32
- КСР	1
самостоятельная работа	59
Промежуточная аттестация	0

	Зачёт
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3.2. Содержание дисциплины

(структурированное по темам (разделам) с указанием отведенного на них количества академических часов и виды учебных занятий)

Наименование разделов и тем дисциплины	Всего (часы)	в том числе			
		Контактная работа (работа во взаимодействии с преподавателем), часы из них			Самостоятельная работа обучающегося, часы
		Занятия лекционного типа	Занятия семинарского типа (практические занятия/лабораторные работы), часы	Всего	
	о ф о	о ф о	о ф о	о ф о	о ф о
Section 1. Introduction to clinical pharmacology.	41	4	8	12	29
Section 2. Special issues of clinical pharmacology in the treatment of various diseases.	66	12	24	36	30
Аттестация	0				
КСР	1			1	
Итого	108	16	32	49	59

Contents of sections and topics of the discipline

Section 1. Introduction to clinical pharmacology.

Topic 1: Basic concepts of clinical pharmacology: pharmacokinetics, pharmacodynamics, drug interactions, adverse drug reactions. Clinical trials of drugs. Fundamentals of evidence-based medicine. Sources of clinical pharmacological information.

Section 2. Special issues of clinical pharmacology in the treatment of various diseases.

Topic 1: Clinical pharmacology of anti-infective drugs

Topic 2: Clinical pharmacology of drugs used in respiratory diseases. Clinical pharmacology of anti-inflammatory drugs.

Topic 3: CF of drugs used in gastrointestinal diseases.

Topic 4: Clinical pharmacology of drugs used in cardiovascular diseases.

Topic 5: Clinical pharmacology of drugs used in hemocoagulation diseases

4. Учебно-методическое обеспечение самостоятельной работы обучающихся

Самостоятельная работа обучающихся включает в себя подготовку к контрольным вопросам и заданиям для текущего контроля и промежуточной аттестации по итогам освоения дисциплины приведенным в п. 5.

Для обеспечения самостоятельной работы обучающихся используются:

Электронные курсы, созданные в системе электронного обучения ННГУ:

Pharmacology (see section Clinical Pharmacology), <https://e-learning.unn.ru/course/view.php?id=10994..>

Иные учебно-методические материалы:

Кукес, В. Г. Клиническая фармакология : учебник / В. Г. Кукес, Д. А. Сычев [и др.] ; под ред. В. Г. Кукеса, Д. А. Сычева. - 6-е изд. , испр. и доп. - Москва : ГЭОТАР-Медиа, 2022. - 1024 с. : ил. - 1024 с. - ISBN 978-5-9704-6807-4. - Текст : электронный // ЭБС "Консультант студента" : [сайт]. - URL : <https://www.studentlibrary.ru/book/ISBN9785970468074.html>

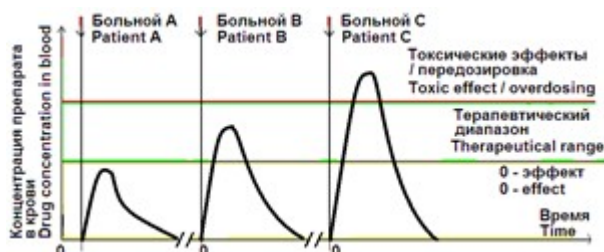
5. Assessment tools for ongoing monitoring of learning progress and interim certification in the discipline (module)

5.1 Model assignments required for assessment of learning outcomes during the ongoing monitoring of learning progress with the criteria for their assessment:

5.1.1 Model assignments (assessment tool - Tasks) to assess the development of the competency ОПК-7:

Task 1***

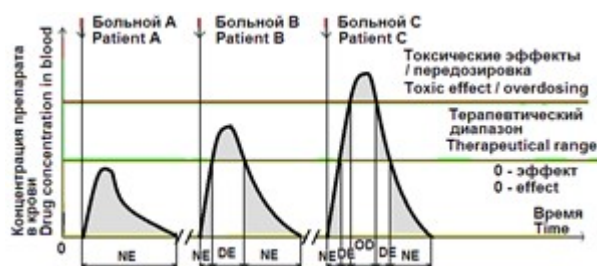
The figure shows pharmacokinetic curves obtained during a trial use of antihypertensive drug A (a drug that lowers blood pressure), which was administered intramuscularly in the same dose once in three patients with hypertension. The arrow marks the moment of injection. All patients complained of headache in the occipital region before treatment, had the same stage of the disease, age, body weight, and an increase in blood pressure to 190/95 mm Hg and parameters of the therapeutic range of the drug.



Questions.

1. Describe what outcome of the trial treatment will be observed in each patient.
2. What adjustment of the drug dose should be in each case.

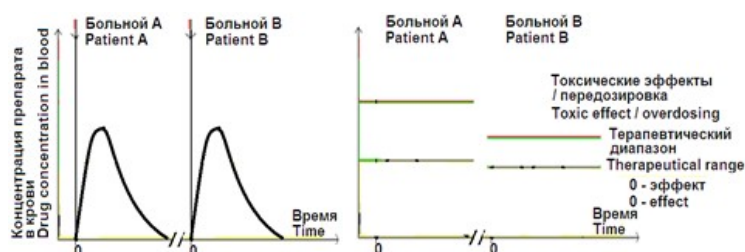
Answer. The effect of the drug on patients can be seen in the same figure with additional highlighting of the stages of the drug's action. The predominant effect at each stage is highlighted in gray. Legend: NE – no effect; DE – ; OD – OverDosage.



In patient A, the drug did not change the condition, since the drug concentration in the blood did not reach the level of the therapeutic range; headache and high blood pressure persisted. Conclusion for case A: The use of the drug was ineffective in achieving the desired effect in the case of a single administration. To achieve the desired effect, it is necessary to titrate the dose upward (for example, increase the next doses by 30%, 50%, etc.) or switch to another drug.

Task 2***

The figure on the left shows pharmacokinetic curves obtained from a trial use of antihypertensive drug A (a drug that lowers blood pressure), which was administered intramuscularly in the same dose once in two patients with hypertension. The arrow marks the moment of injection.



All patients complained of headache in the occipital region before treatment, had the same stage of the disease, age, body weight, and an increase in blood pressure to 190/95 mm Hg. The parameters of the therapeutic range of the drug in these patients are shown in the figure on the right.

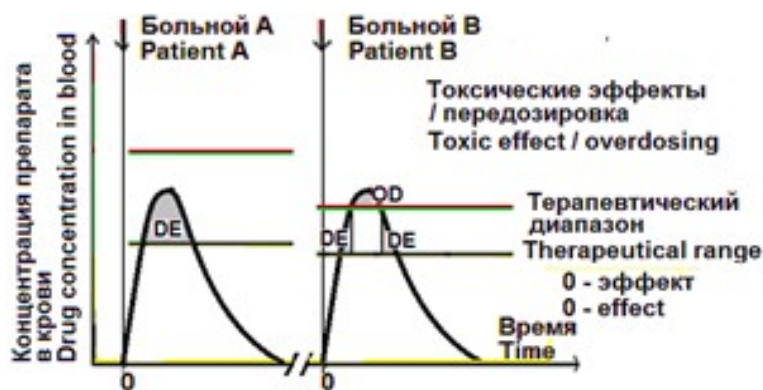
Questions.

- Describe what result of the trial treatment would be observed in each of the patients.
- What is your conclusion about adjusting the dose of the drug in each specific case?

When preparing your answer, use the method of superposition (combination) of the right and left parts of the figure

Answer.

To assess the influence of the width of the therapeutic range on the effect of drugs, the right and left parts of the original figure were combined. Legend: the predominant effect at each stage is highlighted in gray; NE – no effect; DE - Desirable effect; OD -OverDosage.



In patient A, when the concentration reached the therapeutic range and remained there for some time, the blood pressure returned to normal (or showed a clear tendency to normalize) and the headache disappeared.

Conclusion for case A: the drug at this dose is effective in lowering blood pressure with a single administration, no dose adjustment is required.

Patient B. Patient B had a short-term period of normalization (DE) after the drug concentration reached the therapeutic range. However, the concentration continued to grow progressively and after some time exceeded its upper limit. From this moment, overdose manifestations (OD) began, expressed in a decrease in blood pressure below the optimal values for the patient, the appearance of weakness, signs of orthostatic hypotension (symptoms upon standing up: increasing weakness, "darkening in the eyes", possible loss of consciousness, objectively - a sharp decrease in blood pressure), the appearance of diffuse headache. After some time, he felt an improvement in his condition, the headache and weakness passed, he began to get up without orthostatic disorders, blood pressure returned to the optimal values for the patient. These "positive" changes were due to the work of the excretory organs, which contributed to the return of drug concentrations to the therapeutic range (DE). However, then the concentration continued to decrease to the lower limit of the therapeutic range and entered the zero effect zone. From this point on, the patient's blood pressure began to exceed the optimal values and the headache returned. Conclusion for case B: The drug is effective in lowering blood pressure, but for its single use, it is necessary to titrate the dose (e.g., gradually reducing by 10%, 20%, 30%, etc.) until the desired effect is achieved (as in patient A)..

B. Thus, decreasing the width of therapeutic range reduces the safety of drug use, since the possibility of overdose effects increases.

Task 3*

A 72-year-old patient is undergoing inpatient treatment with a diagnosis of bilateral tonsillitis. Objectively: weight 76 kg, height 170 cm, BMI = 27.8 kg/m². Laboratory blood parameters: AST 34 U/L (normal ≤38 U/L), ALAT 36 U/L (normal ≤41 U/L), glucose 5.5 mmol/L (4.2–5.6 mmol/L), creatinine 198 μmol/L (normal: men ≤106 μmol/L; women ≤80 μmol/L), total protein 40 g/L (normal 67–86 g/L).

In accordance with the diagnosis, it was decided to begin treatment with the antibacterial drug amoxicillin.

According to the instructions (grls.rosminzdrav.ru), the drug is excreted by the kidneys by 50-70%, by the liver by 10-20%, the half-life is 1-1.5 hours. In a patient with impaired renal excretory function with a decrease in creatinine clearance ≤ 15 ml / min, the half-life increases to 8.5 hours.

Adult dosages (including elderly patients):

Standard dose: The usual dose ranges from 750 mg to 3 g of amoxicillin per day in several doses. In some cases, it is recommended to limit the dose to 1500 mg per day in several doses.

Dosage for renal failure. Dosage depends on creatinine clearance:

Creatinine clearance ml/min	Dose, mg	Interval between doses, h
>30	No dose changes required: 500	8
10-30	500	12
< 10	500	24

Question.

Draw a conclusion about the optimal dosing regimen for amoxicillin using data on the functional state of the kidneys (based on creatinine clearance).

Take into account that the formula for calculating creatinine clearance (CC) according to Cockcroft and Gault (ml/min):

$$CC * = 88 \times (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, } \mu\text{mol/l}$$

$$CC * = (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, mg/dl}$$

*for women, the result is multiplied by 0.85 (ml/min)

Answer.

Calculating creatinine clearance:

$$CC * = 88 \times (140 - 72 \text{ (years)}) \times 76 \text{ (kg)} / 72 \times 198 \text{ (}\mu\text{mol/l)} = 31.9 \text{ (ml/min)}$$

Conclusion. Despite the signs of decreased renal function (creatinine levels are almost 2 times higher than normal and there is a marked decrease in glomerular filtration (31.9 ml/min), but in the table above it corresponds to a moderate degree of decrease (>30 ml/min; ~30-59 ml/min). According to the instructions for use of the drug, it is recommended to use the usual dosage regimen of amoxicillin: 500 mg 3 times a day.

Task 4**

A 71-year-old female patient is undergoing inpatient treatment with a diagnosis of peritonsillar abscess. Objectively: weight 75 kg, height 165 cm, BMI=27.5 kg/m². Laboratory blood parameters: AST 24 U/L (normal ≤38 U/L), ALAT 26 U/L (normal ≤41 U/L), glucose 5.6 mmol/L (4.2–5.6 mmol/L), creatinine 221 μmol/L (normal: men ≤106 μmol/L; women ≤80 μmol/L), total protein 40 g/L (normal 67–86 g/L).

In accordance with the diagnosis, oral treatment with amoxicillin was started at a dose of 500 mg 3 times a day.

From the instructions for amoxicillin (grls.rosminzdrav.ru <https://cdn.pharm>) the drug is excreted by the kidneys by 50-70%, by the liver by 10-20%, the half-life is 1-1.5 hours. In a patient with impaired renal excretory function, with a decrease in creatinine clearance ≤ 15 ml / min, the half-life increases to 8.5 hours.

Adult dosages (including elderly patients):

Standard dose: The usual dose ranges from 750 mg to 3 g of amoxicillin per day in several doses. In some cases, it is recommended to limit the dose to 1500 mg per day in several doses.

Dosage for renal failure. Dosage depends on the creatinine clearance value:

Creatinine clearance ml/min	Dose, mg	Interval between doses, h
>30	No dose changes required: 500	8
10-30	500	12
< 10	500	24

Questions.

Make suggestions on the optimal treatment regimen for the infectious process and concomitant pathology, using laboratory test data.

Take into account that the formula for calculating creatinine clearance (CC) according to Cockcroft and Gault (ml/min):

$$CC * = 88 \times (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, } \mu\text{mol/l}$$

$$CC * = (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, mg/dl}$$

*for women, the result is multiplied by 0.85 (ml/min)

Answer.

1. An assessment of the possibility of changing the amoxicillin dosage is necessary due to signs of impaired renal function (high blood creatinine levels) and is carried out by checking the creatinine clearance value:

$$CC * = 0.85 \times 88 \times (140 - 70 \text{ (years)}) \times 75 \text{ (kg)} / (72 \times 221) (\mu\text{mol/l}) = 24.7 \text{ (ml/min)}$$

Conclusion. According to the table above, this value corresponds to the average degree of decrease in glomerular filtration (in the range of 10-30 ml/min). In this case, according to the instructions for use of the drug, it is recommended to reduce the doses compared to the original, for example, to 500 mg every 12 hours orally.

2. For possible optimization of pharmacotherapy, it is necessary to pay attention to 1) the presence of a blood glucose level at the upper limit of the norm, which requires additional examination for the possibility of latent diabetes mellitus with appropriate dietary and drug interventions and 2) a decrease in the level of total blood protein, which from the standpoint of clinical pharmacology may require adjustment of the doses of a number of drugs, and from a general clinical standpoint - a search for etiopathogenetic causes of this symptom (malnutrition, liver disease, oncological process, etc.).

TASK 5**

Patient M., 44 years old, is undergoing inpatient treatment with the diagnosis: Acute gangrenous appendicitis, perforation, peritonitis. Concomitant conditions: urolithiasis, chronic kidney disease, unspecified stage. Weight 78 kg, height 180 cm, BMI=24 kg/m². Laboratory blood parameters: AST 35 U/L (normal ≤38 U/L), ALAT 29 U/L (normal ≤41 U/L), glucose 5.1 mmol/L (4.2–5.6 mmol/L), creatinine 316 μmol/L (normal: men ≤106 μmol/L; women ≤80 μmol/L). Due to suspected resistance of microflora, it was decided to prescribe the antibacterial drug tienam from the carbapenem group at a dose of 0.5 g 3 times a day intramuscularly.

Data from the instructions for the drug (grls.rosminzdrav.ru). Tienam includes two main components Imipenem + Cilastatin (Imipenem + Cilastatin). Imipenem belongs to the class of beta-lactam antibiotics thienamycins, and sodium cilastatin is a specific enzyme inhibitor that inhibits the metabolism of imipenem in the kidneys and significantly increases the concentration of unchanged imipenem in the urinary tract. Imipenem is an inhibitor of the synthesis of the bacterial cell wall and has a bactericidal effect on a wide range of pathogenic gram-positive and gram-negative microorganisms, both aerobic and anaerobic. The drug is excreted by the kidneys by 70%, the dosage regimen depends on the severity of the infectious process, the state of the excretory function of the kidneys, and the patient's body weight.

The dosage of the drug for renal failure is carried out according to its severity (assessed by the value of creatinine clearance) see the table. The left column shows the dosages for normal renal function.

Daily dose	Creatinine clearance ml/min		
	41-70	21-40	6-20
1.0 g per day	250 mg every 8 hours	250 mg every 12 hours	250 mg every 12 hours
1,5 g per day	250 mg every 6 hours	250 mg every 8 hours	250 mg every 12 hours
2,0 g per day	500 mg every 8 hours	250 mg every 6 hours	250 mg every 12 hours
3,0 g per day	500 mg every 6 hours	500 mg every 8 hours	500 mg every 12 hours
4,0 g per day	750 mg every 8 hours	500 mg every 6 hours	500 mg every 12 hours

If the body weight decreases below 70 kg, a further proportional reduction of the dose is necessary.

Tienam is administered intravenously only.

Question.

Provide recommendations on the optimal treatment regimen for the infectious process and concomitant pathology, using clinical and laboratory test data.

Take into account that the formula for calculating creatinine clearance (CC) according to Cockcroft and Gault (ml/min):

$$CC * = 88 \times (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, } \mu\text{mol/l};$$

$$CC * = (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, mg/dl}$$

* for women, the result is multiplied by 0.85 (ml/min)

Answer. 1. The patient's creatinine clearance is:

$$CC * = 88 \times (140 - 44 \text{ (years)}) \times 78 \text{ (kg)} / 72 \times 312 \text{ (}\mu\text{mol/l)} = 29.3 \text{ (ml/min)}$$

Conclusion. This value corresponds to the border between C3b (significantly reduced kidney function) and C4 (sharply reduced function) stages of chronic kidney disease. According to the instructions for the drug, with a glomerular filtration rate in the range of 21-40 ml/min, instead of the planned dosage (500 mg 3 times a day), it should be prescribed at a dose of 250 mg every 8 hours (for example, at 6⁰⁰, 14⁰⁰, 22⁰⁰). Warn the staff only about intravenous administration!

2. For possible optimization of pharmacotherapy, it is necessary to pay attention to the presence of kidney pathology with its insufficiency, which requires additional examination with appropriate dietary and medicinal interventions.

TASK 6**

A 36-year-old female patient, weighing 51 kg, is undergoing inpatient treatment with a diagnosis of nonspecific ulcerative colitis, exacerbation. Complications: perforation of the colon, peritonitis. Laboratory blood parameters: creatinine 243 $\mu\text{mol/l}$ (normal 44-97 $\mu\text{mol/l}$ for women). Microbiological examination of the material from the abdominal cavity revealed that the main group of pathogens is a strain of methicillin-resistant *Staphylococcus aureus* (MRSA), resistant to all β -lactam antibiotics. In this regard, it was decided to prescribe the antibacterial vancomycin, a drug from the glycopeptide group. From the instructions for vancomycin (grls.rosminzdrav.ru) - the drug is excreted by the kidneys by 70-80%, impaired renal function slows down the excretion of vancomycin, extending the half-life to 7.5 days. The recommended dosage regimen for vancomycin is 1 g every 12 hours. For patients with impaired renal function, the dose is selected taking into account creatinine clearance. With CC = 10-50 ml / min. vancomycin is prescribed 1 g intravenously by drip 1 time in 3-7 days.

Question. Provide recommendations on the optimal treatment regimen for the infectious process and concomitant pathology, using clinical and laboratory research data. Take into account that the formula for calculating creatinine clearance (CC) according to Cockcroft and Gault (ml/min):

$CC^* = 88 \times (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, } \mu\text{mol/l}$;

$CC^* = (140 - \text{age, years}) \times \text{body weight, kg} / 72 \times \text{serum creatinine, mg/dl}$

*for women, the result is multiplied by 0.85 (ml/min)

Answer. 1. The patient's creatinine clearance is:

$CC^* = 0.85 \times 88 \times (140 - 36 \text{ (years)}) \times 51 \text{ (kg)} / 72 \times 243 \text{ (}\mu\text{mol/l)} = 22.7 \text{ (ml/min)}$

Conclusion. This value corresponds to C4 (severely reduced function) stage of chronic kidney disease.

According to the instructions for the drug, with $CC = 10\text{--}50 \text{ ml/min}$, vancomycin is prescribed at 1 g intravenously by drip once every 3-7 days. These data correspond to the following relationships between the CC level and the frequency of drug administration:

CC value, ml/min	50	40	30	20	10
After how many days should the next dose of the drug be administered	3	4	5	6	7

Thus, vancomycin can be recommended to be administered at 1 g intravenously by drip once every 5-6 days.

2. For possible optimization of pharmacotherapy, it is necessary to pay attention to the presence of kidney pathology with its insufficiency, which requires additional examination with appropriate dietary and medicinal interventions.

Task 7**

Patient I., 50 years old, complains of a feeling of compression behind the sternum with simultaneous discomfort in the left shoulder when walking quickly, especially in cold weather and after eating. The pain stops when stopping or slowing down the pace of walking. He has been ill for 3 years. Judging by the complaints, the disease has not progressed over these years. After examination at the clinic, coronary heart disease was diagnosed: angina pectoris II-III functional class, atherosclerotic cardiosclerosis.

Questions.

1. Select drugs for pharmacotherapy of the patient.
2. Justify the methods for assessing the effectiveness and safety of treatment.

Answer.

1. According to the clinical guidelines "Stable ischemic heart disease" of 2024, conservative therapy is aimed at

- eliminating the symptoms of the disease and
- preventing cardiovascular complications.

Their characteristics are determined by the stage and severity of the disease, as well as in accordance with their classification into the main or alternative group (respectively, "first" or "second line" drugs). To eliminate the symptoms of the disease in stable angina of FC III-IV, in the absence of contraindications, it is recommended to

prescribe first-line drugs such as a combination of beta-blockers (bisoprolol / metoprolol, etc.) with dihydropyridine blockers of "slow" calcium channels (prolonged-release nifedipine, amlodipine, etc.) to achieve the symptoms of coronary heart disease in FC I.

For the prevention of cardiovascular complications, the following are recommended:

- antithrombotic therapy (platelet aggregation inhibitor: acetylsalicylic acid at a dose of 75-100 mg per day; and if it is intolerable - clopidogrel** at a dose of 75 mg per day)
- lipid-lowering therapy in all patients with chronic coronary heart disease as belonging to the category of very high-risk individuals, therefore, statin therapy (atorvastatin, rosuvastatin, pitavastatin) is recommended in doses necessary to achieve the target LDL-C level of less than 1.4 mmol/l and reduce it by 50% from the initial level.

Further treatment adjustment is carried out based on the results of additional studies and the dynamics of the clinical picture.

2. Criteria for the effectiveness of drug therapy: improvement in the patient's condition (absence of shortness of breath and edema, increased tolerance to physical activity, reduction/disappearance of angina attacks), a tendency towards/normalization of Holter ECG monitoring data.

Safety criteria (adverse effects of treatment) are due to the undesirable effects of the drugs used, such as: the appearance of specific abnormalities on the ECG, a tendency to an excessive decrease in blood pressure, instability of glycemia levels, dry wheezing during auscultation of the lungs with the development of bronchospasm when taking β -blockers, etc.

Task 8**

A 51-year-old female patient with ischemic heart disease and post-infarction cardiosclerosis takes atorvastatin at a dose of 80 mg/day to correct lipid metabolism (CH = 10.2 mmol/l (normal 3.780 mmol/l - 7.0 mmol/l)) . After a month of treatment, the patient visited a doctor to purchase the drug to continue the course of treatment. The cholesterol level in the blood was within the normal range: 6.4 mmol/l. When questioned, the patient noted the appearance of myalgia and muscle weakness about 10 days ago.

Questions.

1. What is the most likely cause of the development of these symptoms?
2. Possible actions of the doctor?

Answer.

1. According to the information in the instructions for use of atorvastatin, its use may cause side effects from the musculoskeletal system and connective tissue in the form of myalgia, arthralgia, "swelling" of the joints, joint and back pain, muscle cramps, pain in the muscles of the neck, myopathy, myositis, rhabdomyolysis, immune-mediated necrotizing myopathy.

Rhabdomyolysis is a clinical and laboratory syndrome that is characterized by the destruction of muscle tissue and the entry of decay products into the systemic bloodstream. It can develop with injuries, muscle diseases, infectious diseases and some other conditions. It manifests itself as muscle pain, nausea, vomiting, disorientation, and heart rhythm disturbances. It is often complicated by acute renal failure.

2. At the time of the control examination, the patient had no anamnestic data on the predisposition to rhabdomyolysis (heredity, injuries, use of other drugs with adverse interactions, etc.). Therefore, it is necessary to conduct: a) a targeted survey on the possibility of circumstances predisposing to rhabdomyolysis (see above); b) urgently perform laboratory tests of parameters to assess the function of the liver (ALT, AST, etc.), kidneys (creatinine, creatinine clearance), muscle tissue (CPK), repeatedly within 2-4 days. In the presence of significant deviations, stop the drug and switch to alternative treatment. In case of minor deviations (CPK exceeds the norm by 1.5-2 times), consider the benefit/discontinuation of treatment with the drug. In the absence of deviations, continue treatment. In cases of treatment, monitor the above parameters every 1.5-3 months.

Task 9**

A 52-year-old male patient. Diagnosis: coronary artery disease. Angina pectoris FC III, postinfarction atherosclerosis, heart failure stage 1. Hypertension stage II. As an outpatient, he received pectrol (isosorbide mononitrate) 40 mg once a day, cardiomagnyl 75 mg once a day, enalapril 10 mg once a day, the number of nitroglycerin tablets to relieve angina attacks was 0-0-1 per day. After one month of treatment, complaints appeared about more frequent angina attacks, decreased tolerance to physical activity, which required an increase in the frequency of nitroglycerin intake (up to 1-5 nitroglycerin tablets per day). Upon examination, blood pressure was 140/90 mm Hg, heart rate 85 beats per minute.

Questions.

1. Specify the mechanism of occurrence of new clinical manifestations against the background of the conducted pharmacotherapy.
2. Make suggestions for treatment correction.

Answer.

1. Clinical deterioration is associated with the occurrence of tolerance to nitrates (pectrol) due to long-term use. It is necessary to temporarily stop taking nitrates.
2. According to the clinical guidelines "Stable ischemic heart disease" of 2024, conservative therapy is aimed at
 - eliminating the symptoms of the disease and
 - preventing cardiovascular complications.

Their characteristics are determined by the stage and severity of the disease, as well as in accordance with their assignment to the main or alternative group (respectively, "first" or "second line" drugs).

To eliminate the symptoms of the disease in stable angina of FC III-IV, in the absence of contraindications, it is recommended to prescribe first-line drugs such as a combination of beta-blockers (bisoprolol/metoprolol, etc.) with dihydropyridine blockers of "slow" calcium channels (prolonged-release nifedipine, amlodipine, etc.) to achieve the symptoms of coronary heart disease in FC I.

For the treatment of angina, beta-blockers are prescribed in a minimum dose, which, if necessary, is gradually increased until complete elimination of angina attacks or reaching the maximum permissible dose. When using beta-blockers, the greatest decrease in myocardial oxygen demand and an increase in coronary blood flow are achieved at a heart rate of 55-60 beats per minute. For the prevention of cardiovascular complications, the following are recommended:

- antithrombotic therapy (platelet aggregation inhibitor: acetylsalicylic acid at a dose of 75-100 mg per day; and in case of its intolerance - clopidogrel** at a dose of 75 mg per day)

- lipid-lowering therapy in all patients with chronic coronary heart disease as belonging to the category of persons at very high risk, therefore, statin therapy (atorvastatin, rosuvastatin, pitavastatin) is recommended for them in doses necessary to achieve the target level of LDL-C less than 1.4 mmol/l and to reduce it by 50% from the initial level.

- other drug therapy for concomitant diseases that are significant for the prognosis (post-infarction cardioclerosis, hypertension, diabetes, heart failure) includes the administration of ACE inhibitors (perindopril, etc.) or ARBs (candesartan, telmisartan, etc.).

Conclusion. These data indicate the need to change the patient's pharmacotherapy at the first stage (trial treatment) towards discontinuing pectrol (isosorbide mononitrate) and prescribing a beta-blocker (bisoprolol/metoprolol or others). Given the presence of hypertension, do not use a calcium channel blocker, but continue treatment with an angiotensin-converting enzyme inhibitor, replacing enalapril with perindopril. Coordinate the prescription and dose of statin with the lipid spectrum data and interaction with the selected drugs listed above.

In the future, adjust the treatment based on the results of additional studies and the dynamics of the clinical picture.

Task 10 **

A 41-year-old female patient has been treated in the neurology department for 10 days. Diagnosis: Osteochondrosis of the lumbar spine (L2-L4). Radiculopathy with severe pain syndrome, recurrent. Concomitant: Allergic reaction of the urticaria type from the 5th day of hospitalization.

Admitted with severe pain syndrome, which significantly decreased in intensity in the first 4 days under the influence of treatment. From the fifth day of treatment, the patient developed an allergic reaction of the urticaria type, in connection with which painkillers were canceled and antiallergic pharmacotherapy with Dexamethasone and Chloropyramine was prescribed. As a result, on the 10th day of treatment, the manifestations of urticaria according to subjective and objective data significantly decreased.

Prescription sheet:

[illegible]

Chloropyramine solution 2% 2 ml intramuscularly 2 times a day					+	+	+	+	+	+
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Questions.

1. Assess the drug therapy at the initial stage of treatment.
2. Assess the drug therapy when an allergic reaction occurs.

Answer.

1. At the initial stage of treatment, from the standpoint of analgesic and anti-inflammatory treatment, the choice of drugs from the NSAID groups - Ketorol and Nise (Nimesulide) (COX-2 inhibitor) can be considered correct, since both are indicated for pain in the tissues of the spine of various origins. Indeed, as a result of their combined use, a clinically clear reduction in pain was observed, which is a criterion for the effectiveness of taking all drugs from the NSAID group.

At the same time, the instructions for use of both drugs contain the same indication of a contraindication for simultaneous use with acetylsalicylic acid and other NSAIDs (including COX-2 inhibitors). This means that only one of these drugs should have been selected for treatment. In this case, Nise (Nimesulide) has an advantage, since according to its pharmacological properties, in addition to a good analgesic effect, it also has some antihistamine properties. The latter, inhibiting the activation of the CNS centers and the inflammatory reaction in damaged roots of peripheral nerves, could contribute to enhancing the direct analgesic effect.

The instructions for use of both drugs indicate that they can cause allergic reactions, but in very rare cases. Therefore, it can be assumed that it would be difficult to expect a reliable occurrence of such a reaction, although this should be foreseen.

2. At the second stage of treatment, the cancellation of drugs from the NSAID group and the appointment of the glucocorticoid Dexamethasone and the H1-histamine blocker Chloropyramine is justified from the pathogenetic position. The drugs are prescribed in the appropriate dosages. This gave the expected positive result. But still, one should pay attention to the violation of the introduction of Dexamethasone: glucocorticosteroids are prescribed in the first half of the day. When deciding to continue this treatment, it is necessary to monitor possible side effects of systemic administration of GCS: coagulation disorders (tendency to thrombus formation), increased blood pressure, gastrointestinal bleeding, edema, electrolyte imbalance, osteoporosis.

Task 11**

Women 47 year old came to the polyclinic complaining of a dry cough that had been bothering her for a week. It is known from the anamnesis that the patient has compensated type II diabetes mellitus and arterial hypertension with normalized blood pressure. She has been taking enalapril for the last six months.

Questions.

1. How do you assess the patient's condition?
2. What tactics for treating the patient can you suggest?

Answer. 1. The appearance of a dry cough can be regarded as a manifestation of a side effect of enalapril.

2. Given that the patient has diabetes mellitus, antihypertensive therapy should be started with ACE inhibitors. The drug had the desired effect in the patient, but against this background, its undesirable effect (cough) appeared. Therefore, this drug should be discontinued and another drug with a similar mechanism of action from the group of angiotensin II receptor antagonists, for example, valsartan, should be prescribed.

Task 12***

A 27-year-old male patient developed weakness a week ago, sweating, subfebrile temperature, shortness of breath, and pain in the left side of the chest one week ago. He was treated for acute respiratory viral infection without improvement. Shortness of breath increased, body temperature rose to 39°C, although pain in the left chest decreased.

Objectively: the condition is moderate. The skin is moist, normal color. The left half of the chest lags in the act of breathing. Percussion reveals dullness in the lower left zone. Breathing in this area is not heard. The abdominal organs are unchanged.

Blood analysis: RBC - 4.2×10^{12} , HGB - 140 g/l, WBC - 12×10^9 , IMM% - 2, NEUT% - 80, L - 12, MON - 6, ESR (ESR) - 38 mm/h. Mycobacterium tuberculosis was not detected in the sputum.

Questions.

1. Preliminary diagnosis taking into account the etiology and clinical picture of the disease?
2. Treatment plan taking into account the possibility of obtaining additional examination data?
3. Plan for monitoring the effectiveness and safety of drug therapy?
4. Justification for the choice of the most effective drugs taking into account their interactions?

Answer.

1. Left-sided lobar pneumonia, probably complicated by exudative pleurisy, moderate to severe.
2. In the treatment plan: bed rest; table 10; treatment with a first-line antibiotic (amoxicillin clavulanate orally), mucolytic therapy (ambroxol); symptomatically to reduce temperature acetaminophen. Before starting antibiotic therapy, send sputum to a bacteriological laboratory to determine the etiology of the disease and, if necessary, perform microbiological monitoring. After additional examination – chest X-ray – when determining exudative pleurisy – replace ambroxol with carbocysteine, which has a sufficient anti-inflammatory effect.
3. Monitoring the effectiveness of therapy: a) the effect is considered positive in case of positive dynamics of subjective and objective indicators (reduction of complaints, disappearance of intoxication symptoms, normalization of temperature, laboratory and instrumental examination data, etc.); in this case, leave the treatment unchanged until the next stage of recovery;

b) in the absence of such dynamics, deterioration of the condition - reconsider the diagnosis and / or conduct an additional examination / take into account the microbiological monitoring data and adjust the pharmacotherapy (increase the dose of the original antibiotic / replace it with a 2 / 3 line drug / an antibiotic that is most effective based on the results of microbiological testing) and other possible measures.

Monitoring the safety of therapy: from the first minutes of drug treatment, it is necessary to monitor possible side effects of the selected drugs (see the instructions for their use) based on the subjective sensations of the patient and objective examination data (examination, laboratory and instrumental indicators); if they are detected - a response depending on the type and severity; the most dangerous of them is anaphylactic shock, as one of the variants of allergic reactions, most common when using beta-lactam antibiotics.

4. The choice of drugs for initial treatment can be considered optimal from the standpoint of their interaction: the instructions for the drugs do not indicate any negative effects from their combined use.

Task 13***

Sick woman, 31 years old, was prescribed amoxiclav (amoxicillin with clavulanic acid) orally at a dose of 1000 mg 2 times a day for 10 days for odontogenic maxillary sinusitis. After 7 days, against the background of almost complete healing of sinusitis, loose stools up to 10 times a day, abdominal pain appeared, and the body temperature again increased to 38.60C. During the examination, a general blood test showed leukocytosis up to $18.6 \cdot 10^9 / l$.

History of chronic ulcerative colitis, the last exacerbation was 4 years ago.

Questions.

1. Probable etiopathogenesis of gastrointestinal disorders.
2. Plan for additional examination and treatment, monitoring of desired and undesirable effects of pharmacotherapy.

Answer.

1. The most likely etiopathogenesis is associated with the development of antibiotic-associated diarrhea caused by *Clostridium difficile* (clinical diagnosis "pseudomembranous colitis").

Rationale: a) taking inhibitor-protected penicillins,

b) the presence of risk factors - inflammatory bowel disease,

c) features of the clinical picture - high frequency of stool per day, fever,

d) laboratory data - leukocytosis in the complete blood count.

2. Indicated:

- hospitalization in an infectious diseases hospital;

- conducting a stool test to detect toxins A and B and microbial bodies of *Clostridium Difficile*;

bed rest, diet No. 4, vancomycin (500 mg 4 times a day) +/- metronidazole (500 mg 3 times a day) + enterol (1 capsule 2 times a day) for a 10-day course of treatment;

monitoring of efficacy and safety:

- consider treatment effective if the following signs are present: no complaints, elimination of diarrhea, normalization of temperature and general blood test results; reduction and then complete disappearance of toxins A and B in the results of stool analysis;
- absence of signs of side effects of the drugs received by the patient and their adverse interactions (according to the instructions for these drugs and clinical data).

Task 14***

A 28-year-old woman with a 18-week pregnancy and a furuncle on the chin developed a fever of 39°C on the fifth day of outpatient treatment with ampicillin orally at 250 mg 3 times a day, facial deformation was noted due to significant swelling of the tissues of the chin and submental area. The patient was urgently hospitalized in the maxillofacial surgery clinic. On examination: a furuncle measuring 1.5 x 1.5 cm in size in the chin area, painful on palpation, in the center - at the site of the removed core - a crater-shaped ulcer. The surrounding soft tissues are edematous, the skin of the chin and submental area is hyperemic, tense. In the hyperemic zone, a fluctuation symptom. Due to complicated skin and subcutaneous infection, moxifloxacin (a drug from the fluoroquinolone group) was prescribed intravenously by drip at 400 mg once a day. A clear positive effect was noted 48 hours after the start of treatment.

Questions.

1. Assess the effectiveness of drug therapy at the outpatient stage.
2. Assess the effectiveness and safety of drug therapy in the hospital.

Answer.

1. Drug therapy was not effective at the outpatient stage.
2. Drug therapy was effective at the inpatient stage. From the patient's point of view and the absence of negative drug reactions, the therapy was safe. However, given the pregnancy, not everything is so clear.

2.1. Ampicillin. According to the instructions for the drug, it has one of the following indications for use:

- Infectious and inflammatory diseases caused by microorganisms sensitive to ampicillin: including skin and soft tissues (erysipelas, impetigo, secondarily infected dermatoses).

Pregnancy is not included in the list of contraindications for prescription.

There is also a special indication that "the drug may be used during pregnancy according to indications in cases where the benefit to the mother outweighs the potential risk to the fetus."

Recommended dosages: Adults - 250 mg 4 times a day; if necessary, the dose is increased to 3 g / day. Thus, ampicillin was prescribed according to indications in the correct dose (1.5 g / day). At the same time, the drug was ineffective. Possible reasons.

- a) The wrong dosage regimen was chosen: 750 mg per day instead of the required 1.0 grams or more.
- b) Pharmacodynamic monitoring, which involved assessing the clinical effect of treatment after two days of treatment, was not conducted. If there is no effect, it is recommended to either increase the dose (according to

the instructions for the drug, the dose can be increased to 3 g/day) or replace the first antibiotic with an alternative drug.

c) Microbiological monitoring, which involved identifying the causative agent of the disease, its sensitivity to specific antibiotics in the laboratory and determining its minimum inhibitory concentration, was not conducted.

2.2. Moxifloxacin. Indications: Infectious and inflammatory diseases caused by microorganisms sensitive to moxifloxacin (including complicated infections of the skin and subcutaneous structures), etc. Contraindications: Pregnancy and breastfeeding, etc.

This means that the drug was contraindicated for the patient.

Task 15***

A 42-year-old woman was prescribed a drug to relieve asthma attacks. During a follow-up examination, she reported that the attacks were relieved within a few minutes after two consecutive inhalations of the drug, but soon after that, an irregular heartbeat, tachycardia, and tremors of the extremities appeared.

Questions.

1. What groups of drugs are considered emergency aid for an asthma attack?
2. Identify the pharmacological group used and name its main representatives.
3. What mechanism is responsible for the listed side effects?
4. Your suggestions for adjusting the treatment and assessing the effectiveness of the treatment.

Answer.

1. Short-acting beta2-adrenergic agonists.
2. Short-acting beta-adrenergic agonists, salbutamol, and fenoterol.
3. Activation of beta1-adrenergic receptors of the heart and nerve structures (salbutamol has highly lipophilic properties and, therefore, easily penetrates the blood-brain barrier; fenoterol does not have pronounced lipophilic properties and penetrates less through this barrier).
4. Switch to a modern regimen of drug use, starting with
 - basic therapy: intensive anti-inflammatory therapy with inhaled glucocorticoids in combination with long-acting beta2-adrenergic receptor agonists;
 - to stop attacks - short-acting beta2-adrenergic receptor agonists, for example, salbutamol, but not more than 1 time;
 - with further adjustment based on the results obtained.

The results of the adjustment are considered effective when the frequency of attacks is reduced by more than 2 times, with an optimum of complete cessation.

Task 16***

Patient M., 34 years old. At the age of 32, he first experienced asthma attacks, coughing in the evenings without signs of a cold. He was treated with beta-adrenergic agonists in the Central Regional Hospital with a diagnosis of bronchial asthma with a good effect. A year later, he was hospitalized with the same diagnosis to adjust the treatment. During the examination, eosinophilia (up to 9%) was detected in the blood test, and scarification tests were also positive for house dust allergens.

Questions.

1. What are your suggestions for adjusting the treatment?
2. Efficacy and safety criteria?
3. What are your recommendations for activities in the patient's apartment?

Answers. 1. The patient has bronchial asthma with a predominant allergic component (J45.0), mild, in the acute stage. As a basic therapy, it is recommended to consider the appointment of a combined bronchodilator (selective beta2-adrenergic agonist and local glucocorticosteroid) on a regular basis with the use of a selective beta-2-adrenergic agonist as needed to relieve asthma attacks.

In parallel, it is possible to recommend Allergen-specific immunotherapy - one of the main methods of pathogenetic treatment of IgE-mediated allergic diseases, consisting in long-term regular use of a therapeutic allergen in order to induce immune tolerance.

2. A. Criteria for treatment effectiveness:

- for basic therapy: reduction in the intensity of symptoms, reduction in the need for the use of drugs, prevention of the development of bronchial asthma attacks;

- for allergen-specific immunotherapy: reduction in the sensitivity of the body to the causative allergen, reduction in the intensity of symptoms, reduction in the need for the use of drugs, prevention of the development of bronchial asthma in patients with an allergic component;

B. Safety criteria for both types of therapy: absence of side effects on the drugs used.

3. Elimination hygienic measures in the patient's apartment: removal of causative allergens (house dust, etc.) refers to etio-pathogenetic methods of treating allergies and is suitable for bronchial asthma of the allergic phenotype.

Task 17**

A 34-year-old man was delivered to the hospital emergency department by an ambulance team. According to the doctor, the ambulance was called to a patient lying unconscious on the street. The patient had a diabetic record booklet for insulin treatment. Upon examination, the patient's condition was severe. Consciousness was impaired. The skin was pale and moist, with traces of subcutaneous injections 5-7 cm below the navel. Muscle twitching. The eyeballs are of normal density. Breathing is shallow, there is no smell of acetone. Pulse is 98 per minute, rhythmic. Blood pressure is 135/90 mm Hg. The abdomen is soft, painless on palpation. The liver is not enlarged.

Urine analysis: sugar and acetone are not detected. Blood sugar is 1.9 mmol / l.

Questions.

1. Initial clinical diagnosis.
2. Treatment plan, methods of monitoring effectiveness.

Answer.

1) Type 1 diabetes mellitus complicated by hypoglycemic coma.

2) The goal of treatment is to stop hypoglycemic coma with normalization of consciousness and biochemical parameters, followed by continuation of treatment in the compensation phase. Urgently administer 20 to 80 ml of 40% glucose solution intravenously by jet stream. If the patient has not regained consciousness, then administer 300-500 ml of 5% glucose solution intravenously by drip. With intravenous drip administration of glucose, 0.1% solution of 0.5 ml of adrenaline can be administered, as adrenaline increases the glucose content in the blood due to the breakdown of glycogen in the liver and increases the permeability of cell membranes for glucose.

After consciousness has returned, feed the patient slowly absorbed carbohydrates (bread, porridge, potatoes). If the blood sugar level rises to 10-11 mmol / l, do not administer insulin, waiting for the next scheduled injection.

To prevent this side effect of insulin therapy, explain to the patient the need to strictly adhere to the regularity of meals, as well as the need to have carbohydrate products (chocolate, candy, crackers, etc.) with them, which can be taken prophylactically at the first symptoms of impending hypoglycemia.

Task 18**

Patient D., 82 years old. Diagnosis: Ischemic heart disease: angina pectoris, Functional Class III, diffuse atherosclerosis. Atherosclerosis of the aorta, coronary, cerebral arteries. Hypertension stage III, risk of Cardiovascular Complications 4. Chronic Heart Failure IIB.

Drug therapy chart

Drug	Day of hospitalization	1	2	3	4	5	6	7	8
Concor 5 mg ½ tab. 1 time/day		+	+	+	+	+	+	+	+
Nitrosorbide dinitrate 10 mg 2 times/day		+	+	+	+	+	+	+	+
Veroshpiron/Spironolacton 25 mg 3 times/day		+	+	+	+	+	+	+	+
Enalapril 20 mg ½ tab. 2 times/day		+	+	+	+	+	+	+	+
Verapamil 40 mg 3 times/day		+	+	+	+	+	+	+	+
Aspirin 500 mg ¼ tab. 1 time/day		+	+	+	+	+	+	+	+
Glucose solution 5% 200 ml				+	+	+	+	+	+

Furosemide solution 1% 2 ml intravenous jet 4 ml after drip	+	+	+	+						
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- Betaloc ZOK - (INN) metoprolol succinate,
- Coraxan - (INN) ivabradine
- Pectrol - (INN) isosorbide mononitrate

Questions.

1. Data on the possibility of side effects of the drug Betaloc ZOK.
2. Data on the possibility of side effects of the drug Furosemide.
3. Data on the possibility of side effects of the drug Perindopril.
4. Methods of studying the control of the effectiveness and safety of the prescribed pharmacotherapy.

Answer.

1. Side effects when taking Betaloc (metoprolol) - bradycardia. AV blocks, decreased blood pressure, bronchospasm, development of hypoglycemia.
2. Side effects when prescribing Furosemide: decreased levels of sodium, potassium, chlorine, magnesium ions in the blood, development of metabolic acidosis, increased uric acid, glycemia levels.
3. Side effects of Pirindopril (ACE inhibitor): hyperkalemia, decreased blood pressure, angioedema (Quincke's edema), cough.
4. Criteria for the effectiveness of drug therapy: improvement in the patient's condition (reduction in shortness of breath and edema, increased tolerance to physical activity, reduction/disappearance of angina attacks), a tendency towards/normalization of Holter ECG monitoring data. Safety criteria (adverse effects of treatment): the appearance of specific abnormalities on the ECG, a tendency towards excessive decrease in blood pressure, disturbances in the electrolyte composition of the blood, acid-base balance, instability of glycemia levels, dry wheezing during auscultation of the lungs with the development of bronchospasm when taking β -blockers.

Task 20***

A 47-year-old patient developed gastric bleeding 2 hours after the intravenous administration of 10,000 U of heparin. In an emergency blood test for coagulability, the activated partial thromboplastin time (APTT) was 126 seconds (normal: 25–37 seconds), which was regarded as a complication of therapy due to an overdose of heparin.

Questions.

1. Specify the mechanism by which an adverse reaction to the administration of heparin occurs
2. What should be the safety monitoring of pharmacotherapy?
3. Suggest measures to correct the therapy being administered

Answer.

1. The adverse reaction developed as a result of an overdose of heparin, the pharmacodynamic action of which is due to its binding to antithrombin III, which is a natural inhibitor of a number of blood coagulation factors, thereby blocking their enzymatic activity aimed at thrombus formation. Excess of such action causes various adverse reactions, including bleeding from various areas of the body, in this case from the stomach.
2. Safety monitoring should take into account the APTT value. It should increase by no more than 1.5-2 times from the initial level, that is, up to 37.5-74 sec. The actual value was 126 sec, which was 3.4-5 times higher than the norm and once again confirmed the heparin overdose. According to the instructions for the drug, the first dose of heparin for intravenous administration is usually 5000 U (in the patient 10,000 U), and the subsequent ones are monitored/selected based on the dynamics of the APTT value.
3. According to the instructions for use of the drug, in case of minor bleeding caused by an overdose of sodium heparin, it is sufficient to stop using it. In case of extensive bleeding, excess sodium heparin is neutralized with protamine sulfate (1 mg protamine sulfate per 100 IU of sodium heparin).

Assuming that an adverse reaction to heparin (bleeding) has revealed a hidden pathology - peptic ulcer disease or its previous gastropathy, this requires referring the patient for endoscopic bleeding control as a method of treating ulcerative bleeding (Clinical guidelines. Peptic ulcer of the stomach and duodenum. Moscow, 2024). As part of this or other measures to achieve hemostasis, intravenous administration of a proton pump inhibitor, such as omeprazole or analogs, is recommended to stop bleeding and prevent its recurrence.

Assessment criteria (assessment tool — Tasks)

Grade	Assessment criteria
outstanding	The solution is given in a volume exceeding the volume of the program for mastering the discipline, in compliance with the necessary sequence of actions; the answer contains all entries, tables, drawings, drawings, graphs, and calculations correctly and accurately; error analysis was performed correctly.
excellent	The solution is given in full in compliance with the necessary sequence of actions. The answer contains all entries, tables, figures, drawings, graphs, and calculations correctly and accurately. Error analysis performed correctly.
very good	The solution is given in full, following the required sequence of actions. There are 1-2 errors in the answer
good	The solution is given in full, following the required sequence of actions. There are 2-3 errors in the answer
satisfactory	The solution is not given in full, but the volume of the completed part is such that it allows us to obtain the correct results and conclusions. Errors were made during the work.
unsatisfactory	The solution is not given in full or the volume of work performed does not allow us to draw correct conclusions
poor	No solution provided. Inability to assess the completeness of knowledge due to the student's

Grade	Assessment criteria
	refusal to answer.

5.1.2 Model assignments (assessment tool - Test) to assess the development of the competency OIK-7:

*1. Clinical Pharmacology is

A .the science that studies the interaction of drugs with human organism; laws and regularities (patterns) of such interaction as bases for using of Pharmacotherapy for treatment.

B. studies the interaction of drugs with any organism.

C. bases for using of Pharmacotherapy for treatment.

D. scientific and practical industry, engaged in the search, production, research, storage, manufacture and delivery of drugs.

***2. What branches of medicine (as a science) is clinical pharmacology related to?

A. pharmacy.

B. (basic) pharmacology.

C. pharmacotherapy.

D .all of above.

*3. Pharmacokinetics is (brief definition):

A .the body's effect on the drug.

B. the effect of the drug on the body.

C. study of drug transport to the target organ.

D. study of the mechanisms of action of drugs.

*4. Pharmacodynamics is (brief definition):

- A .the effect of the drug on the body.
- B. the action of body on the drug.
- C. study of drug transport to the target organ.
- D. study of the mechanisms of action of drugs.

***5. Enteral routes of administration include**

- A .all routes related to the gastrointestinal tract and oral cavity..
- B. sublingual, oral and subcutaneous routes.
- C. intramuscular, intravenous and subcutaneous routes.
- D. intranasal and inhalation routes.

***6. Parenteral routes of administration include**

- A .all non-gastrointestinal routes.
- B. sublingual, oral and rectal routes.
- C. sublingual, oral and subcutaneous routes of administration.
- D. rectal, intranasal and inhalation routes.

*****7. The mechanisms of action of drugs may include the effect on:**

- A. receptor.
- B. enzyme.
- C. transmembrane ion channel and membrane-bound transporter.
- D. direct physical and chemical interactions.
- E .all of the above.

*****8. The type of desired pharmacological action includes achieving:**

- A. recovery in case of acute illness.
- B. relief of exacerbation of a chronic disease.

C. the transition of a chronic disease into remission and maintenance of this condition for a long time / permanently.

D. deterioration of the patient's clinical condition at the beginning of treatment due to the use of potent effects (chemotherapy, surgery) with subsequent improvement in the condition, as in cases A-D.

E .all of the above (depending on the specifics of the case).

*****9. Methods for monitoring the desired pharmacological action, important for optimal treatment, include the assessment of the dynamics of:**

A. complaints of the patient.

B. the physical condition of the patient.

C. laboratory analysis of the patient.

D. instrumental data of the patient.

E .all of the above in various combinations.

*****10. The type of undesirable pharmacological action includes manifestations of effects:**

A. overdose/intoxication.

B. deterioration of tissue / organ functions according to the list of side effects in the instructions for a specific drug.

C. allergic reactions and anaphylactic shock.

D. addiction.

E. harmful effects on the fetus when a pregnant woman uses any specific drug.

F .all of the above.

***11. Main side effect of tetracyclines in elderly people:**

A .liver dysfunction;

B. agranulocytosis;

C. pseudomembranous colitis;

- D. convulsive syndrome;
- E. renal dysfunction.

***12. Drug of choice for the treatment of antibiotic-associated diarrhea:**

- A. erythromycin;
- B. aminopenicillin;
- C. vancomycin;
- D. tetracycline;
- E. furazolidone.

***13. Development of drug-inherent hepatitis during antibiotic therapy is caused by the use of:**

- A. gentamicin;
- B. vancomycin;
- C. ampicillin;
- D. cefuroxime;
- E. clarithromycin.

***14. Vancomycin side effect:**

- A. increased transaminases;
- B. arterial hypotension;
- C. ototoxic effect;
- D. dry cough;
- E. prolongation of the QT interval on the ECG.

***15. Levomycetin side effect leading to fatality in 100% of cases:**

- A. aplastic anemia;

- B. toxic hepatitis;
- C. allergic reaction;
- D. interstitial nephritis;
- E. peripheral polyneuropathy.

***16. Mucolytic drug is**

- A. theophylline
- B. salmeterol
- C. intal
- D .ambroxol
- E. sodium cromoglycate

***17. Mucolytic drug is**

- A .acetylcysteine
- B. sodium cromoglycate
- C. intal
- D. theophylline
- E. salbutamol

***18. Preferred therapy in stage ii of bronchial asthma:**

- A .medium-dose inhaled glucocorticoids/long-acting β 2-agonists (selective beta 2-adrenergic agonists)
- B. tiotropium
- C. low-dose inhaled glucocorticoids
- D. theophylline intravenously
- E. short-acting beta-2 agonist as needed or its combination with ipratropium bromide.

***19. Preferred first-step therapy for asthma treatment:**

- A. Short-acting beta-2 agonist as needed or combination with ipratropium bromide
- B. Low-dose inhaled glucocorticoids
- C. Medium-dose inhaled glucocorticoids/long-acting β_2 -agonists (selective beta 2-adrenergic agonists)
- D. Tiotropium
- E. Intravenous theophylline

****20. Preferred fifth-step for asthma therapy:**

- A. Low-dose inhaled glucocorticoids/long-acting β_2 -agonists (selective beta 2-adrenergic agonists)
- B. Low-dose inhaled glucocorticoids
- C. theophylline intravenously
- D. consider additionally tiotropium, omalizumab
- E. short-acting beta-2 agonist as needed or its combination with ipratropium bromide

****21. What adverse effects are most dangerous during treatment with statins?**

- A. digestive system disorders;
- B. allergic reactions;
- C. myalgia, myopathy, rhabdomyolysis;
- D. headache, dizziness;
- E. proteinuria.

Answers to tests

- 1. A 2. D 3. A
- 4. A 5. A 6. A
- 7. E 8. E 9. E
- 10. F 11. A 12. C
- 13. E 14. E 15. A

16. D 17. A 18. A

19. B 20. C,D 21. C

Assessment criteria (assessment tool — Test)

Grade	Assessment criteria
outstanding	100% correct answers
excellent	90 – 99 % correct answers
very good	80 – 90 % correct answers
good	70-80 % correct answers
satisfactory	50 – 70 % correct answers
unsatisfactory	20 – 50 % correct answers
poor	0 – 20 % correct answers

5.1.3 Model assignments (assessment tool - Report-presentation) to assess the development of the competency OPIK-7:

Approximate outline of the report/presentation/ (select the relevant points for preparation):

1. Definition.
2. Classification.
3. Pharmacokinetic features.
4. Pharmacodynamic features: mechanisms of action, pharmacological effects, undesirable side effects.
5. Indications for use.
6. Contraindications for use.
7. Features of interaction with other drugs.
8. Features of dosage in childhood and old age, during pregnancy and breastfeeding.
9. Features of monitoring of efficacy and safety in pharmacotherapy.
10. Significance/relevance of use for medical practice in the specialty.

Topics of the reports/presentations

1. The importance of the connection between pharmacokinetic and pharmacodynamic processes for individualization of pharmacotherapy.
2. The concept of the three main sections of clinical pharmacology. Significance for rational pharmacotherapy.
3. General scheme of pharmacokinetic processes. Absorption of drugs: factors determining the rate and completeness of absorption (properties of the drug, site of absorption, state of the body). Peculiarities in children.
4. Advantages and disadvantages of drug entry into the body using different routes of administration.
5. Circulation of drugs in the blood. The importance of binding to proteins and competition for binding to proteins. Their influence on the implementation of the pharmacological effect.

6. Distribution of drugs in body tissues. Volume of distribution, practical significance of the concept. Peculiarities in newborns and the elderly.
7. Biotransformation of drugs: phases, factors determining the rate of the process (peculiarities in children). The concept of enzymopathies.
8. Elimination of drugs from the body (renal clearance, total clearance). Peculiarities in children.
9. Pharmaceutical interactions of drugs.
10. Drug interactions at the stages of pharmacokinetics.
11. Pharmacodynamic drug interactions.
12. Effects of repeated drug administration (cumulation, tolerance, addiction, allergy).
13. Dose-dependent drug side effects. Correction methods.
14. Dose-independent drug side effects. Correction methods.
15. Drugs and pregnancy. Embryotoxic and teratogenic effects of drugs. List of drugs that are unacceptable for use, high- and moderate-risk drugs.
16. Features of pharmacodynamics and pharmacokinetics during breastfeeding.
17. Features of pharmacodynamics, pharmacokinetics and drug dosing in the elderly.
18. Use of clinical pharmacology data to individualize pharmacotherapy. The importance of patient characteristics for choosing drugs.

Assessment criteria (assessment tool — Report-presentation)

Grade	Assessment criteria
outstanding	The report contains complete information on the topic presented, based on mandatory literary sources and modern publications; the speech is accompanied by high-quality demonstration material (re-port/presentation); the student is fluent in the content, presents the material clearly and competently; answers questions and comments from the audience freely and correctly; fits exactly within the regulations (4 - 7 minutes); all requirements for the report/presentation have been met
excellent	The report contains complete information on the topic presented ; the speech is accompanied by high-quality demonstration material (report/presentation); the student is fluent in the content, presents the material clearly and competently; answers questions and comments from the audience freely and correctly; fits exactly within the regulations (4 - 7 minutes); all requirements for the report/presentation have been met
very good	The topic presented is covered, but the report contains minor inaccuracies on the topic

Grade	Assessment criteria
	presented; the performance is accompanied by demonstration material (presentation); the speaker presents the material clearly and competently; answers questions and comments from the audience in a reasoned manner, but the speaker made minor errors in presenting the material and answer-ing questions; design requirements are 80% fulfilled
good	The presented topic is covered, but the report contains incomplete in-formation on the presented topic; the performance is accompanied by demonstration material (presentation); the speaker presents the material clearly and competently; answers questions and comments from the audience in a reasoned manner, but the speaker made minor errors in presenting the material and answer-ing questions; design requirements are 80% fulfilled
satisfactory	The speaker demonstrates superficial knowledge on the chosen topic and has difficulty using the scientific-conceptual apparatus and termi-nology of the course; accompanying demonstration material is incomplete and illogical; registration requirements are fulfilled by less than 80%
unsatisfactory	The report has significant gaps on the topics presented and is based on unreliable information; the speakers made fundamental errors when presenting the material; work does not meet requirements
poor	Lack of knowledge on the topic presented; work not presented

5.2. Description of scales for assessing learning outcomes in the discipline during interim certification

Шкала оценивания сформированности компетенций

Уровень сформированности компетенций (индикатора достижения компетенций)	плохо	неудовлетворительно	удовлетворительно	хорошо	очень хорошо	отлично	превосходно
	не зачтено		зачтено				
<u>Знания</u>	Отсутствие знаний теоретического материала. Невозможность оценить полноту знаний вследствие отказа обучающегося от ответа	Уровень знаний ниже минимальных требований. Имели место грубые ошибки	Минимально допустимый уровень знаний. Допущено много негрубых ошибок	Уровень знаний в объеме, соответствующем программе подготовки. Допущено несколько негрубых ошибок	Уровень знаний в объеме, соответствующем программе подготовки. Допущено несколько несущественных ошибок	Уровень знаний в объеме, соответствующем программе подготовки. Ошибок нет.	Уровень знаний в объеме, превышающем программу подготовки.
<u>Умения</u>	Отсутствие минимальных умений.	При решении стандартных задач не	Продемонстрированы основные	Продемонстрированы все	Продемонстрированы все	Продемонстрированы все	Продемонстрированы все основные

	Невозможность оценить наличие умений вследствие отказа обучающегося от ответа	продемонстрированы основные умения. Имели место грубые ошибки	умения. Решены типовые задачи с негрубыми ошибками. Выполнены все задания, но не в полном объеме	основные умения. Решены все основные задачи с негрубыми ошибками. Выполнены все задания в полном объеме, но некоторые с недочетами	основные умения. Решены все основные задачи. Выполнены все задания в полном объеме, но некоторые с недочетами	основные умения. Решены все основные задачи с отдельными несущественными недочетами, выполнены все задания в полном объеме	умения. Решены все основные задачи. Выполнены все задания, в полном объеме без недочетов
<u>Навыки</u>	Отсутствие базовых навыков. Невозможность оценить наличие навыков вследствие отказа обучающегося от ответа	При решении стандартных задач не продемонстрированы базовые навыки. Имели место грубые ошибки	Имеется минимальный набор навыков для решения стандартных задач с некоторыми недочетами	Продемонстрированы базовые навыки при решении стандартных задач с некоторыми недочетами	Продемонстрированы базовые навыки при решении стандартных задач без ошибок и недочетов	Продемонстрированы навыки при решении нестандартных задач без ошибок и недочетов	Продемонстрирован творческий подход к решению нестандартных задач

Scale of assessment for interim certification

Grade		Assessment criteria
pass	outstanding	All the competencies (parts of competencies) to be developed within the discipline have been developed at a level no lower than "outstanding", the knowledge and skills for the relevant competencies have been demonstrated at a level higher than the one set out in the programme.
	excellent	All the competencies (parts of competencies) to be developed within the discipline have been developed at a level no lower than "excellent",
	very good	All the competencies (parts of competencies) to be developed within the discipline have been developed at a level no lower than "very good",
	good	All the competencies (parts of competencies) to be developed within the discipline have been developed at a level no lower than "good",
	satisfactory	All the competencies (parts of competencies) to be developed within the discipline have been developed at a level no lower than "satisfactory", with at least one competency developed at the "satisfactory" level.
fail	unsatisfactory	At least one competency has been developed at the "unsatisfactory" level.
	poor	At least one competency has been developed at the "poor" level.

5.3 Model control assignments or other materials required to assess learning outcomes during the interim certification with the criteria for their assessment:

5.3.1 Model assignments (assessment tool - Case task) to assess the development of the competency ОПК-7

ASSESSMENT OF DRUG CHOICE, EFFICIENCY AND SAFETY OF DRUG TREATMENT (PROTOCOL)

Directions: Try to complete it by filling each space with necessary data or underline/circle the proper point.

Abbreviations: M - medicament; SE - side effects; PD - pharmacodynamics; PK - pharmacokinetics; PT - pharmacotherapy; PC - pharmaceutical; po - peroral; pc~ percutaneous; iv — intravenous; im — intramuscular.

1. PATIENT'S PERSONAL DETAILS

Date of filling in the Case History _____ Case History № _____ Department № / Ward№ ____/

1.1. Patient's name _____ 1.2. Age _____

1.3. Weight _____ kg 1.4. Height _____ cm 1.5. Date of admission

1.6. Clinical diagnosis (A. Main Disease, B. Complications, C. Associated diseases) _____

1.7. Disease severity: *mild moderate severe*

1.8. Anamnesis of the disease (. Times of diseases onset, their complications, dates of surgery etc.):

1.9. History of a patient (general information essential for assessment of drug therapy): _____

1.10. Allergic reactions: No Yes. Non-medicine manifestations:

1.11. Anamnesis of drug allergy: (1) anaphylactic shock, 2) urticaria, 3) angioneurotic oedema, 4) serum sickness, 5) pruritis, 6) another (insert or underline proper point, indicate M-allergen, e.g.: "1-Levorin"; "5(pruritis)-Nospa") _____

1.12. Gastro-intestinal system (GIS) and organs of elimination (liver, kidney) (anamnesis, physical and laboratorial data):

GASTRO-INTESTINAL SYSTEM:

KIDNEYS:

_ Anamnesis _____

Blood creatinin_____ mmol/1 (N; >N; <N). **Blood urea:**_____ mmol/1 (N; >N; <N)

Reberg test (glomerular filtration)_____ ml/min (N; >N; <N). **Other analyses:**_____

_____ **LIVER.** Anamnesis: _____

Bilirubin (total/conjugated) __/__ mmol/1 (N; >N; <N). **Protrombin index**_____ % (N; >N; <N). **ALT**_____ (N; >N; <N). **AST** _____ (N; >N; <N). **Protein** (total)_____ (N; >N; <N). **Others** _____

ADDITIONAL DATA important for treatment (POINTS OF NOTE) _____

1.13. PAST HISTORY-Previously used drugs (medicines). You must indicate a mode of administration (Orally, SL, IM, SC, IV etc.), dose, frequency and duration of introduction; indicate efficiency of therapy (according point **1.14.**) and extent of SE (mark their clinical manifestations) – according to point **1.15**; dates of the onset - end of treatment. E.g.: **1.13.2 - "Streptomycin im. 0,3 g x 2 x 12 days, 1/-2 (tinnitus)" 03/01/2001 – 15/01/2001.**

1.13.

1 _____
_____.

1.13.

2 _____
_____.

1.13.

3 _____
_____.

1.13.

4 _____
_____.

1.13.

5 _____
_____.

1.13.

6 _____
_____.

1.13.7 _____
_____.

1.13.

8 _____
_____.

1.13.

9 _____
_____.

1.13.1

0 _____
_____.

1.14. Evaluation of efficacy of M (specific effect)	Code
1. No effects (according to objective and subjective data)	0
2. No subjective improvement but some objective	1
3. Improvement tendency (incomplete recovery)	2
4. Complete recovery	3
5. Desirable effect is achieved but there are some excessive side effects (SE)	4

6. Unknown effect	7
1.15. Evaluation of side effects (SE)	
1. No SE according to objective and subjective data	0
2. There is mild SE (no subjective sensations , not dangerous)	-1
3. There is subjective and objective manifestations of SE, but they are not dangerous	-2
4. Dangerous SE (it is a need for intensive therapy)	-3
5. Unknown effect.	-7

1.16. List of drugs, used during in-patient treatment (according to point 1.13)

1.16.

1 _____
_____.

1.16.

2 _____

1.16.

3 _____
_____.1.16.4_____
_____.

1.16.

5 _____
_____.1.16.6_____
_____.1.16.7_____
_____.1.16.8_____

1.16.

9 _____
_____.

1.16.1

0 _____

2. PLAN OF OPTIMAL PT OF THE PRESENT DISEASE

2.1. The basis of the treatment plan in accordance with

- the etiology and
- pathogenesis of the disease:

if necessary, use the materials of both

- the results of the actual case (anamnesis, lab.and instr.data, etc.) and
- the standards of treatment/medical publications, etc.

Best mode – to make a graph of the pathogenesis of disease (see the next page).

Alternative - descriptive mode.

Comparison of selection of groups of drugs acc. to etio-pathogenesis and in real case

<i>Ethio-pathogen.plan for the selection of groups of drugs</i>	<i>Graph of the pathogenesis of disease</i>	<i>Real treatment</i>
<i>Etiologic&Risk Factor:</i> <i>Groups of drugs</i>		
<i>Pathogenesis:</i> <i>Groups of drugs</i>		

<i>Syndromes:</i> <i>Groups of drugs</i>	
<i>Symptoms/signs:</i> <i>Groups of drugs</i>	
<i>Miscellaneous:</i> <i>Groups of drugs</i>	

Conclusion of 2.1

2.1.1. Main disease (syndrome): _____

Objective of treatment (for main (basic) disease/ syndrome):

a. Recovery __; b. Remission ____ ; c. Other _____

2.1.2. Treatment goals (for syndromes / symptoms)

	Syndromes/ symptoms No 1 :	Syndromes/ symptoms No 2 :	Syndromes/ symptoms No 3 :	Syndromes/ symptoms No 4 :	Syndromes/ symptoms No 5 :

Result of treatment	a b c	a b c	a b c	a b c	a b c
----------------------------	------------------------	------------------------	------------------------	------------------------	------------------------

Here: a. Recovery b. Remission c. Other

2.1.3. Associated disease(s) – syndromes, that may influence the treatment of the main disease (syndrome):

	Syndromes/ disease No 1 :	Syndromes/ disease No 2 :	Syndromes/ disease No 3 :	Syndromes/ disease No 4 :	Syndromes/ disease No 5 :
Result of treatment	a b c	a b c	a b c	a b c	a b c

Here: a. Recovery b. Remission c. Other

2.1.3. Main groups of medical treatment:

- | | | |
|----|----|----|
| 1) | 2) | 3) |
| 4) | 5) | 6) |
| 7) | 8) | 9) |

2.2. A CHOICE BETWEEN GROUPS OF Medicines (M) (see item 2.1.3) Elimination of group because:

a) M. contra-indicated to children/elderly patients or patients with secretion organs disease:

b) M. with non-sufficient efficiency for this disease

gravity:_____

c) M. which badly penetrate into affected

organs/tissues:_____

d) M. with allergic complications in past medical history, or in case of possibility of cross- allergic reactions.

e) M. with high possibility of toxic effects: _____

f) M. which were ineffective in previous treatment (in case of proper application): _____

Conclusion on items 2.1 –2.2. Best Group are: _____(1st Gr.), _____(2nd Gr.)
 _____(3d Gr.).

2.3. CHOOSE THE BEST M. FOR THE TREATMENT OF MAIN (ESSENTIAL) DISEASE/ SYNDROME (between M1-M4 in 1st Gr., and M5-M6 in 2nd Gr. comparing descriptions of PK, SE, etc.)

Characteristics of 1st group of M.	M1	M2	M3	M4
Degree of penetration into target organ				
Bioavailability, %				
First pass effect				
Half-life time (t _{1/2}) min (hour, day)				
Possibility and frequency of SE				
Cost of M.				
Others (mark)				
Characteristics of listed group of M.	M5	M6	M7	M8
Degree of penetration into target organ				
Bioavailability, %				
First pass effect				
Half-life time (t _{1/2}),min (hour, day)				
Possibility and frequency of SE				
Cost of M.				

Others (mark)				

In this way, following M. is/are the optimal M. (explain why)_____

2.4. A CHOICE OF ADMINISTRATION MODE (for 2 optimal M.) according item 2.3. Optimal mode is showing by the "+", chosen mode - by circling the proper variant.

2.4.1. M1. _____

Condition	Mode: po, pc, iv, im, inhal etc. _____
Pregnancy	
Location of a pathological process	
Gastrointestinal tract state	
Patient's age	
Form of M.	

2.4.2. M2. _____

Condition	Mode: po, pc, iv, im, inhal etc. _____
Pregnancy	
Location of a pathological process	
Gastrointestinal tract state	
Patient's age	
Form of M.	

Comments (if it is needed) _____

2.5. A CHOICE OF M. DOSE AND DOSES REGIME (insert or circle the proper variant)

2.5.1. M1 _____ Dose (according to the age) _____

Correction of the dose according to specific conditions:	Specific dose
- weight: to decrease, to increase, no change, unknown	=
- clearance: to decrease, to increase, no change, unknown	=
- function of eliminating organs: to decrease, to increase, no change, unknown unk.	=
- $t_{1/2}$: to decrease, to increase, no change, unknown	=
- disease gravity: to decrease, to increase, no change, unknown	=
- administration mode:	=

RESULT: Dose = _____; Frequency_of administration _____

2. M2 _____ Dose (according to the age) _____

Correction of the dose according to specific conditions:	Specific dose
- weight: to decrease, to increase, no change, unknown	=
- clearance: to decrease, to increase, no change, unknown	=
- function of eliminating organs: to decrease, to increase, no change, unknown unk.	=
- $t_{1/2}$: to decrease, to increase, no change,	=

unknown	
- disease gravity: to decrease, to increase, no change, unknown	=
- introduction mode:	=

RESULT: Dose = _____; Frequency Frequency_of administration

2.6. POSSIBLE DURATION of COURSE of M. ADMINISTRATION. The terms depend on:

	Diagnosis	Gravity	Probable SE
<i>Example (Amiodarone in pt. suffering from ventr. prem. beats of III grad. because of ischemic heart dis. and associated thyrotoxicosis)</i>	<i>“before improvement of pts condition” or “the whole life”</i>	<i>“only 15 days”</i>	<i>“contraindicated because of high risk of thyroid disease recurrence”</i>
M1 _____			
M2 _____			

2.7. CHOICE OF METHODS AND TERMS OF THE EVALUATION OF THE PT EFFICIENCY:

Clinical criteria of desirable effects		Term	Laboratory analyses et other criteria	Term
<i>Examples</i>	<i>Reduction of the heart attacks freq. Reduction of BP. to 110/80 mm. No signs of glycemia (thirst etc.)</i>	<i>Daily Daily Daily</i>	<i>ECG (absence of premature beat) Glycemia level decreasing to 7 mmol/l:</i>	<i>One time in 1-5 days 6 times in a day</i>
M1				
M2				

2.8. CHOICE OF METHODS AND TERMS OF THE EVALUATION OF THE PT:

Clinical criteria for Side Effects		Term	Laboratory analyses et other criteria	Term
Examples	<i>Rise of the heart attacks freq.</i>	<i>Daily</i>	<i>E.C.G</i>	<i>2 times/day</i>
	<i>Reduction of A.T. below 90/60 mm.</i>	<i>Daily</i>		
	<i>Appearance of a high risk of premature beats</i>	<i>Daily</i>	<i>Glucose level decreasing to 4 mmol/l</i>	<i>6 times/ day</i>
M1				
M2				

2.9. NECESSITY FOR ADDITIONAL M. FOR POTENTIATION OF M1 – M2 DESIRABLE EFFECTS OR DECREASE IN THEIR SIDE EFFECTS

	M. that increases desirable effects	M. that reduces SEs	not required
M1			
M2			

Comments (if it is needed): _____

2.10. A CHOICE OF M. FOR TREATMENT OF ASSOCIATED DISEASES/Syndromes

('+' - synergism; "—" - antagonism; "±" -indifferent, "0" - unknown effects, ? - doubtful)

M. name:	M5	M6	M7
Necessity in acute period	yes no ?	yes no ?	yes no ?
PD interaction with M 1	+ — ± 0	+ — ± 0	+ — ± 0
PD interaction with M2	+ — ± 0	+ — ± 0	+ — ± 0

2.11. CONCLUSION CONCERNING A PLAN OF OPTIMAL PT IN PRESENT CASE

(compare with data in items 2.1.3 and 2.4.1)

For treatment of the essential disease/syndrome are optimal:

M1 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.

Dose_____ Course duration _____

M2 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.

Dose_____ Course duration _____.

For potentiation of M 1 or M 2 effects (or SE reduction) are optimal:

M3 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.

Dose_____ Course duration _____

M4 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.

Dose_____ Course duration _____

For treatment of a present disease are optimal:

M5 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.
Dose_____ Course duration _____

M6 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.
Dose_____ Course duration _____

M6 (name)_____ Administration mode: pc, po, iv, im, inhal, etc.
Dose_____ Course duration _____

-

3. EXAMINATION OF ACTUAL PT (see item 1.16)

During analysis use data of pharmacological textbooks, pharmacological handbooks such as ‘Vidal’ or ‘Encyclopedia of drugs’, base data in Internet etc.

3.1. PD CHARACTERISTICS OF USED M. (2 basic M.) (You must compare the effects a) desirable (as in books) and b) observing in actual case: "++" - exceeding the desirable ones, "+" – the same, "-" - below the desirable ones, "0"- no data)

M1:_____PD principle of action:_____

Effects of M.:	Desirable	Observing
Duration		++ + — 0
Start of action		++ + — 0
Maximum of action		++ + — 0
Clinical manifestations (mark the signs)		++ + — 0
Physical data (mark what)		++ + — 0
Laboratory data (mark what)		++ + — 0

M2:_____PD principle of action:_____

Effects of M.:	Desirable	Observing
Duration		++ + — 0

Start of action		++ + — 0
Maximum of action		++ + — 0
Clinical manifestations (mark what signs)		++ + — 0
Physical data (mark what)		++ + — 0
Laboratory data (mark what)		++ + — 0

3.2 PK CHARACTERISTICS OF USED M. (according to literature data and those observing (or expecting) in an actual case)

PK parameter	M1		M2	
	In Books	Estimated	In Books	Estimated.
Bioavailability, %		++ + — 0		++ + — 0
Binding proteins, %		++ + — 0		++ + — 0
Volume of distribution		++ + — 0		++ + — 0
t $\frac{1}{2}$, min. (hour, day)		++ + — 0		++ + — 0
Therapeutic concentration, mg/1		++ + — 0		++ + — 0
Toxic concentration, mg/1		++ + — 0		++ + — 0
		0		0

3.3. COMPARISION OF ADMINISTRATION MODES OF M. (recommended according to the clinical and PC characteristics and used in an actual case).

Modes	M1		M2	
	Recommended.	Used	Recommended	Used

Routes of administration				
Daily dose				
Numbers of daily administration				
Dependence on food				
Rate of introduction (i.v. etc.)				

3.4. CLINICAL AND LABORATORY METHODS OF EVALUATION OF PT EFFICIENCY

	Desirable effects	Observing or no
M1		Code according to item 1.14:_____
M2		Code according to item 1.14:_____

3.5. CLINICAL AND LABORATORY METHODS OF EVALUATION OF THE SAFETY OF PT

	Side effects	Observing or no
M1		Code according to item 1.15:_____
M2		Code according to item 1.15:_____

3.6. SPECIAL FEATURES OF DRUGS INTERACTION (Using information of lit. and computer base data to compare desirable combination of M. and unwanted ones. M1 and M2 mean the basic M., M3 - M10 – additional M acc. to 1.16). Example: M1 Tetracycline + M2 Almagel: PD "±" PK "±" PC "-" Designations: "+" - synergism, "-" - antagonism, "±" -indifferent, "0" - unknown effect. In case of synergism or antagonism to mark the type of interaction: PD, PK, PC

	M1	M2	M3	M4	M5
M1		PD "+" "-" "±" "0"	PD "+" "-" "±" "0"	PD "+" "-" "±" "0"	PD "+" "-" "±" "0"
		PK "+" "-"	PK "+" "-"	PK "+" "-"	

		"±""0"	"±""0"	"±""0"	PK"+" "-" "±""0"
		PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"
M2	PD"+" "-" "±""0"		PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"
	PK"+" "-" "±""0"		PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"
	PC"+" "-" "±""0"		PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"
	M6	M7	M8	M9	M10
M1	PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"
	PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"
	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"
M2	PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"	PD"+" "-" "±""0"
	PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"	PK"+" "-" "±""0"
	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"	PC"+" "-" "±""0"

3.7. GENERAL CONCLUSION ABOUT EFFICIENCY AND SAFETY OF PT IN AN ACTUAL CASE

1. Choice of drugs **answers / answers partly / didn't answer** about purposes of treatment (as well as etiology / pathogenesis, diagnosis of disease)

(Commentary/

explanation _____

_____)

2. Purposes of treatment ***are achieved*** / ***are not fully achieved*** / ***are not achieved***

(Commentary/

explanation _____

_____)

3. The presence of SE: **NO** **YES**____

(Commentary/

explanation _____

_____)

4. Drug interactions: ***are correct*** or

PC incompatibility _____

PD incompatibility _____

PK incompatibility _____

5. Suggestions for optimizing the PT

PT does not require adjustment

Correct the dose of a drug _

1) _____

2) _____

3) _____

4) _____

Find a solution to question(s) of

1) _____

2) _____

3) _____

4) _____

-

4. PRESCRIPTIONS FOR BASIC MEDICAL PREPARATIONS *acc. to items 1.13 a. 1.16 (individual doses, forms, mode of use acc. to item 3.3, detailed signatures).*

Rp.:

Rp.:

Rp.:

Rp.:

Rp.:

Rp.:

Rp.:

Rp.:

Rp.:

The study was carried out by _____ from country _____

Faculty _____ **Year** _____ **Group** _____

Teacher's mark: 5 — 4 — 3 — 2 — 1 —

Teacher's Notes :

Assessment criteria (assessment tool — Case task)

Grade	Assessment criteria
pass	The task has been completed in full
fail	The work has not been submitted

5.3.2 Model assignments (assessment tool - Control questions) to assess the development of the competency ОПК-7

1. Clinical pharmacology: position among medical sciences, connection and interaction with basic pharmacology and pharmacotherapy, aims and objectives.
2. The importance of the connection between pharmacokinetic and pharmacodynamic processes for individualization of pharmacotherapy.
3. The concept of the three main sections of clinical pharmacology. Significance for rational pharmacotherapy.

4. General scheme of pharmacokinetic processes. Absorption of drugs: factors determining the rate and completeness of absorption (properties of the drug, site of absorption, state of the body). Peculiarities in children.
5. Advantages and disadvantages of drug entry into the body using different routes of administration.
6. Circulation of drugs in the blood. The importance of binding to proteins and competition for binding to proteins. Their influence on the implementation of the pharmacological effect.
7. Distribution of drugs in body tissues. Volume of distribution, practical significance of the concept. Peculiarities in newborns and the elderly.
8. Biotransformation of drugs: phases, factors determining the rate of the process (peculiarities in children). The concept of enzymopathies.
9. Elimination of drugs from the body (renal clearance, total clearance). Peculiarities in children.
10. Pharmaceutical interactions of drugs.
11. Drug interactions at the stages of pharmacokinetics.
12. Pharmacodynamic drug interactions.
13. Effects of repeated drug administration (cumulation, tolerance, addiction, allergy).
14. Dose-dependent drug side effects. Correction methods.
15. Dose-independent drug side effects. Correction methods.
16. Drugs and pregnancy. Embryotoxic and teratogenic effects of drugs. List of drugs that are unacceptable for use, high- and moderate-risk drugs.
17. Features of pharmacodynamics and pharmacokinetics during breastfeeding.
18. Features of pharmacodynamics, pharmacokinetics and drug dosing in the elderly.
19. Use of clinical pharmacology data to individualize pharmacotherapy. The importance of patient characteristics for choosing drugs.
20. Principles of antibiotic therapy, the importance of clinical pharmacology.
21. Clinical pharmacology of beta-lactam antibiotics (penicillins, cephalosporins, carbapenems).
22. Clinical pharmacology of aminoglycosides.
23. Clinical pharmacology of tetracyclines
24. Clinical pharmacology of macrolides.
25. Clinical pharmacology of glycopeptide antibiotics.

26. Clinical pharmacology of quinolones.
27. Clinical pharmacology of sulfonamide drugs (combined and non-combined).
28. Clinical pharmacology of antiviral drugs (for the treatment of influenza and acute respiratory viral infections).
29. Clinical pharmacology of antifungal drugs.
30. Clinical pharmacology of painkillers (non-steroidal anti-inflammatory drugs; antidepressants, B vitamins, anticonvulsants, narcotic analgesics, etc.).
31. Clinical pharmacology of glucocorticoid drugs.
32. Clinical pharmacology of bronchodilators.
33. Clinical pharmacology of mucolytic, expectorant, antitussive drugs.
34. Clinical pharmacology of antacids, H₂-histamine blockers.
35. Clinical pharmacology of proton pump inhibitors.
36. Clinical pharmacology of drugs that enhance the regeneration of the gastrointestinal mucosa.
37. Clinical pharmacology of drugs that affect the motility of the gastrointestinal tract.
38. Clinical pharmacology of alpha-blockers (prazosin, doxazazin).
39. Clinical pharmacology of beta-blockers.
40. Clinical pharmacology of calcium antagonists.
41. Clinical pharmacology of angiotensin-converting enzyme inhibitors and angiotensin-2 receptor blockers.
42. Clinical pharmacology of nitrates.
43. Clinical pharmacology of antiarrhythmic drugs.
44. Clinical pharmacology of diuretics.
45. Clinical pharmacology of hypertensive drugs (norepinephrine, mesaton, caffeine, angiotensinamide).
46. Clinical pharmacology of lipid-lowering drugs. Statins. PCSK9 inhibitors.
47. Clinical pharmacology of lipid-lowering drugs. Fibrates and omega-3 fatty acids. Ezetimibes.
48. Clinical pharmacology of drugs affecting platelet aggregation and adhesion.
49. Clinical pharmacology of drugs increasing blood clotting.
50. Clinical pharmacology of drugs decreasing blood clotting.

Assessment criteria (assessment tool — Control questions)

Grade	Assessment criteria
pass	Outstanding The level and scope of knowledge exceeds the training program, without errors. Excellent The level of knowledge corresponds to the training program, without errors. Very good The level of knowledge corresponds to the training program. One or two minor errors were made. Good The level of knowledge corresponds to the training program. Several minor errors were made Satisfactory The minimum acceptable level of knowledge. Many minor errors were made.
fail	Unsatisfactory The level of knowledge is below the minimum requirements. There were major errors Poor Knowledge is lacking.

6. Учебно-методическое и информационное обеспечение дисциплины (модуля)

Основная литература:

1. Кулес В.Г. Клиническая фармакология : учебник / Кулес В.Г.; Сычев Д.А. - Москва : ГЭОТАР-Медиа, 2022. - 1024 с. - ISBN 978-5-9704-6807-4., <https://e-lib.unn.ru/MegaPro/UserEntry?Action=FindDocs&ids=807894&idb=0>.

Дополнительная литература:

1. Вебер. Клиническая фармакология : учебник / Вебер. - Москва : ГЭОТАР-Медиа, 2023. - 784 с. - ISBN 978-5-9704-6909-5., <https://e-lib.unn.ru/MegaPro/UserEntry?Action=FindDocs&ids=869045&idb=0>.
2. Оковитый С.В. Клиническая фармакология и фармакотерапия : учебник / Оковитый С.В.; Куликов А.Н. - Москва : ГЭОТАР-Медиа, 2022. - 848 с. - ISBN 978-5-9704-6291-1., <https://e-lib.unn.ru/MegaPro/UserEntry?Action=FindDocs&ids=808171&idb=0>.

Программное обеспечение и Интернет-ресурсы (в соответствии с содержанием дисциплины):

ЭБС «Юрайт». Режим доступа: <http://biblio-online.ru>.

ЭБС «Консультант студента». Режим доступа: <http://www.studentlibrary.ru>.

ЭБС «Лань». Режим доступа: <http://e.lanbook.com/>.

ЭБС «Znaniyum.com». Режим доступа: www.znaniyum.com.

7. Материально-техническое обеспечение дисциплины (модуля)

Учебные аудитории для проведения учебных занятий, предусмотренных образовательной программой, оснащены мультимедийным оборудованием (проектор, экран), техническими средствами обучения, компьютерами.

Помещения для самостоятельной работы обучающихся оснащены компьютерной техникой с возможностью подключения к сети "Интернет" и обеспечены доступом в электронную информационно-образовательную среду.

Программа составлена в соответствии с требованиями ФГОС ВО по направлению подготовки/специальности 31.05.01 - General Medicine.

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Программа одобрена на заседании методической комиссии от 28 ноября 2024, протокол № №9.