ЛД-16 ИН

Federal State Budgetary Educational Institution of
Higher Education
"NORTH OSSETIAN STATE MEDICAL ACADEMY" of the
Ministry of Health of the Russian FEDERATION

ДОКУМЕНТ ПОДПИСАН
ЭЛЕКТРОННОЙ ПОДПИСЬЮ

Сертификат:
16F3AE70D8619CDF7F857E4D5D6A82512DE9ACF2
Владелец: Ремизов Олег Валерьевич
Действителен: с 06.12.2021 до 06.03.2023

APPROVED
Rector of FSBEI HE NOSMA
MOH Russia
O.V. Remizov
«30» March 2022

**EDUCATIONAL TRAINING PROGRAM OF THE DISCIPLINE**

**"CLINICAL PHARMACOLOGY"**

the main professional educational program of higher education-specialty program in the specialty 31.05.01 General Medical, approved on 30.03.2022.

Form of education Full-time
The period of development 6
Department of Pharmacology with Clinical Pharmacology

Vladikavkaz, 2022

When developing the work program , the disciplines are based on:

1. Federal State Educational Standard for the specialty 31.05.01 Medical business, approved by the Ministry of Education and Science of the Russian Federation on February 9, 2016, No. 95

2. Curricula of the OPOP in the specialty 31.05.01 Medical business
ЛД-16-01-17 ИН
ЛД-16-02-18 ИН
ЛД-16-03-19 ИН
ЛД-16-04-20 ИН

approved by the Academic Council of the Federal State Budgetary Educational Institution of the Ministry of Health of the Russian Federation on March 30, 2022, Protocol No. 6

The working program of the discipline was approved at the meeting of the Department of Pharmacology with Clinical Pharmacology dated March 21, 2022, Protocol No. 10.

The working program of the discipline was approved at the meeting of the central coordinating educational and Methodological Council dated March 22, 2022, Protocol No. 4.

The working program of the discipline was approved by the Academic Council of the Federal State Budgetary Educational Institution of the Ministry of Health of the Russian Federation on March 30, 2022, Protocol No. 6

Developers:
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V.A. Morozov - Head of the Department of Pharmacy, K.L. Khetagurov North Ossetian State University, Ph.D., Associate Professor

**The content of the work program**

1. name of the discipline;
2. the list of planned learning outcomes in the discipline, correlated with the planned results of the development of the educational program;
3. indication of the place of discipline in the structure of the educational program;
4. the volume of the discipline in credit units indicating the number of academic or astronomical hours allocated for contact work of students with the teacher (by type of training sessions) and for independent work of students;
5. the content of the discipline, structured by topics (sections) with an indication of the number of academic or astronomical hours allocated to them and types of training sessions;
6. the list of educational and methodological support for independent work of students in the discipline;
7. fund of evaluation funds for conducting intermediate certification of students in the discipline;
8. the list of basic and additional educational literature necessary for the development of the discipline;
9. the list of resources of the information and telecommunication network "Internet" (hereinafter referred to as the "Internet"), necessary for the development of the discipline;
10. methodological guidelines for students on the development of the discipline;
11. list of information technologies used in the implementation of the educational process in the discipline, including a list of software and information reference systems (if necessary);
12. description of the material and technical base necessary for the implementation of the educational process in the discipline.
13. conducting educational activities using e-learning and distance learning technologies

**2. The list of planned results of training in the discipline and the results of the development of the educational program**

| No. n/a | Number / / index from the computer and | The content of the discipline (or its sections) | Development results | | |
|---|---|---|---|---|---|
| | | | To know | be able to | own |
| 1 | 2 | 3 | | | |
| 1. | OPK-1 | General questions of clinical pharmacology | The subject and objectives of clinical pharmacology. Sections of clinical pharmacology (clinical pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology).<br><br>The concept of pharmacotherapy. Types of pharmacotherapy<br>Basic principles of rational pharmacotherapy. Stages of pharmacotherapy.<br>Pharmacological and allergological history<br><br>Pharmacological test. Commitment the patient's treatment is compliance.<br>Efficiency and safety assessment medicines. Principles of development efficiency control programs and safety of medicines. Evaluation effects of medicines on quality lives.<br>Undesirable reactions during application medicines. WHO classification.<br>Interaction of medicines.<br><br>Rational, irrational and dangerous combinations. Features of pharmacokinetics and pharmacodynamics of medicinal products in pregnant and fetal. Categories of medicinal products funds according to the degree of risk to the fetus according to WHO:<br>Principles of pharmacotherapy in pregnant women.<br>Features of pharmacokinetics and pharmacodynamics of medicinal products in lactating women.<br>Features of pharmacokinetics and pharmacodynamics of medicinal products in elderly and senile patients.<br>Calculation of the dose of the drug in patients elderly and senile age.<br>Drug overdose:<br>diagnostics, first aid, basic principles therapy (prevention of absorption, strengthening deductions). | Calculate the main pharmacokinetic parameters :<br><br>volume<br><br>distributions ($V_d$), constant speeds<br><br>eliminations ($K_{elim}$), period semi - elimination and (half-life) ($t_{1/2}$), clearance (Cl), bioavailability (F).<br>Calculate load and maintenance dose of LV.<br><br>Calculate the dose LV in patients with CPN.<br>Spend<br><br>dose adjustment LV in patients with violation functions liver. | The algorithm for evaluating the main parameters of the pharmacokinetics of LS<br><br>Methodology carrying out pharmacological test.<br><br>Methodology feeds notifications about NPR. |
| 2. | OPK-5 | Clinical and pharmacological approaches to selection and application medicinal products funds at diseases internal organs. | Clinical pharmacology of antimicrobial drugs. Antibiotics: penicillins, cephalosporins, carbopenems, aminoglycosides, macrolides, lincosamides, tetracyclines, glycopeptides, linezolid, fluoroquinolones, co trimoxazole, metronidazole. Antifungal.<br><br>Antiviral. Antimicrobial spectrum activity. Principles of choice (empirical and etiotropic), determination of the dosage regimen in depending on the localization of infection and severity conditions, kidney function. Assessment methods efficacy and safety of antimicrobial<br>drugs. Diagnostics and prevention of NLR.<br>Combination of antimicrobial medicinal means and interaction in the joint appointment with drugs of other groups. | Choose effective,<br><br>safe medicinal funds in according to<br><br>clinical diagnosis on based on standards Pharmacotherapy, list<br>ZHNVLS, formulary the system; count | The selection algorithm medicinal tools, medicinal forms and<br><br>mode dosing in depending on clinical situations |

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| | | | Clinical and pharmacological approaches, taking into account nosology, individual characteristics | load and supporting | |

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| | | | pharmacokinetics and pharmacodynamics, to the choice of antifungal and antiviral drugs.<br>Clinical pharmacology of psychotropic drugs. Psychostimulants are Nootropics. Anxiolytics. Neuroleptics. Anticonvulsant medications. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for mental and neurological diseases: sleep disorders, neuroses, depression, schizophrenia, manic-depressive psychosis, epilepsy, migraine, multiple sclerosis, Parkinson's disease, transient disorders of cerebral circulation (by ischemic or hemorrhagic types). Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with the combined administration of drugs and in combination with other drugs.<br>Clinical pharmacology of drugs affecting hemostasis. Antiplatelet agents. Direct anticoagulants. Indirect anticoagulants. Fibrinolytics. Synthetic selective inhibitor of activated factor X (Xa) Drugs that increase blood clotting. Fibrinolysis inhibitors. Iron preparations. Means to stop bleeding. Principles of selection and determination of the dosage regimen depending on the state of the coagulating, anti-clotting, fibrinolytic system of the patient, data on the pharmacodynamics and pharmacokinetics of drugs and their efficacy in diseases of the liver, kidneys, gastrointestinal tract, hematopoietic organs, cardiovascular system, use in various periods of pregnancy, in lactating women and the elderly (taking into account treatment standards and the list of VED).Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of nonsteroidal anti-inflammatory drugs. Clinical pharmacology of drugs affecting bronchial patency. Anti-inflammatory anti-asthmatic agents: inhaled glucocorticoids, systemic glucocorticoids. Stabilizers of mast cell membranes, leukotriene inhibitors. Antitussive and expectorant agents. Antihistamines. Pulmonary surfactants. Principles of drug selection, determination of routes of administration, methods of drug delivery to the respiratory tract and rational dosage regimen of drugs, taking into account the reversibility of airway obstruction, severity of bronchial obstruction, sputum characteristics, cardiovascular system, pharmacokinetics, factors that change sensitivity to the drug, treatment standards and the list of VED. The concept of step-by-step therapy of bronchial asthma. Diagnosis, correction and prevention of NLR. Syndrome decreased receptor sensitivity (tachyphylaxis, internalization and decreased regulation), causing the development of resistance to beta-stimulants, methods of its correction and prevention. Methods for evaluating effectiveness and safety. Assessment of the quality of life. The concept of compliance (or adherence to treatment). Possible interactions with their combined administration and in combination with drugs of other groups. | to calculate the dose of medicines for patients with chronic renal insufficiency, impaired liver function, elderly and senile age; to choose the dosage form to determine the optimal dosage regimen for a particular patient; to develop a program for monitoring the effectiveness and safety of prescribed drugs, choosing the necessary set of routine (survey, examination) and special laboratory and functional research methods, including therapeutic drug monitoring and research of quality of life indicators, in order to assess pharmacodynamic effects medicinal products, their pharmacokinetic parameters; interpret the data obtained; choose methods adequate control of the effectiveness and safety of treatment and predict the risk of developing NLR; identify, classify, register NLR when prescribing the most common medications and suggest ways to prevent and correct them; fill out documents on notification of the development of undesirable drug reactions; take measures to increase the patient's adherence to medication; diagnose and treat overdose with medications | |

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| | | | Clinical pharmacology of nonsteroidal anti-inflammatory drugs. Clinical pharmacology of cytostatics and immunosuppressants. Anti-inflammatory drugs: NSAIDs, basic, slow-acting anti-inflammatory drugs. Remedies used for gout. Drugs that affect the structure and mineralization of bones. Painkillers (paracetamol, tramodol), opioids (morphine), ketamine, fentanyl. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for rheumatic diseases: systemic lupus erythematosus, rheumatoid arthritis, deforming osteoarthritis, osteoporosis, gout. Principles of the choice of routes of administration, dosage regimen depending on the features of the inflammatory process: localization, intensity, taking into account chronopharmacology. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of drugs affecting the organs of the digestive system. Antacids. Blockers of H2-histamine receptors. Proton pump inhibitors. Prokinetics. Drugs for the treatment of functional disorders of the intestine. Enzyme preparations. pancreatin. Drugs used for diarrhea: loperamide. Laxatives. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, pharmacotherapy standards in gastroenterology and the list of VED, to the selection and use of medicines for diseases of the digestive system: gastro-esophageal reflux disease, gastric ulcer and duodenal ulcer, liver cirrhosis, chronic pancreatitis, constipation and diarrhea, irritable bowel syndrome, ulcerative colitis and disease Crown. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of drugs affecting vascular tone and hypolipidemic agents. Medications that lower vascular tone: agonists of central α2-adrenergic receptors and I1- imidazoline receptors α-blockers, ACE inhibitors, angiotensin antagonists receptors, direct renin inhibitor, beta-blockers, slow calcium channel blockers, venous dilators, pentoxifylline.<br>Hypolipidemic drugs: statins, fibrates. Fibrinolytics. Painkillers: NSAIDs, tramadol, opioids. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for coronary artery disease (angina pectoris, myocardial infarction, unstable angina), hyperlipidemia and hypertension. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups. | | |

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| | | | Clinical pharmacology of drugs affecting the main functions of the myocardium and diuretics. Antiarrhythmic drugs. Inotropic drugs: Diuretics. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for frequent and life-threatening rhythm disorders and chronic heart failure. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of drugs used in endocrinology. Antidiabetic drugs. Thyroid hormone preparations and antithyroid drugs. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for type 1 and 2 diabetes mellitus, hypothyroidism, hyperthyroidism. Therapy of emergency conditions in endocrinology. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups. | | |
| 3. | OPK-6 | General questions of clinical pharmacology | The subject and objectives of clinical pharmacology. Sections of clinical pharmacology (clinical pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology).<br>The concept of pharmacotherapy. Types of pharmacotherapy Basic principles of rational pharmacotherapy. Stages of pharmacotherapy. Pharmacological and allergological history Pharmacological test. The patient's adherence to treatment is compliance. Evaluation of the effectiveness and safety of medicines. Principles of development of programs for monitoring the effectiveness and safety of medicines. Assessment of the effect of medicines on the quality of life. | Calculate the main pharmacokinetic parameters: volume of distribution($V_d$), elimination rate constant ($K_{elim}$), period half-elimination (half-life) ($t_{1/2}$), clearance (Cl),bioavailability (F). | The algorithm for evaluating the main parameters of pharmacokinetics of drugs by the methodology of conducting a pharmacological test.<br>The methodology for submitting a notification of the NPR. |

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| | | | Undesirable reactions when using medications. WHO classification. Interaction of medicines. Rational, irrational and dangerous combinations. Features of pharmacokinetics and pharmacodynamics of drugs in pregnant women and fetus. Categories of medicines according to the degree of risk to the fetus according to WHO. Principles of pharmacotherapy in pregnant women. Features of pharmacokinetics and pharmacodynamics of drugs in lactating women.<br>Features of pharmacokinetics and pharmacodynamics of drugs in elderly and senile patients. Calculation of the dose of the drug in elderly and senile patients. Drug overdose: diagnosis, first aid, basic principles of therapy (prevention of absorption, enhanced excretion). | Calculate the loading and maintenance doses of LV. Calculate the dose of LV in patients with CRF.<br>To correct the dose of LV in patients with impaired liver function. | |
| 4. | OPK-7 | Clinical and pharmacological approaches to the selection and use of medicines for diseases of internal organs. | Clinical pharmacology of antimicrobial drugs. Antibiotics: penicillins, cephalosporins, carbopenems aminoglycosides, macrolides, lincosamides, tetracyclines, glycopeptides, linezolid, fluoroquinolones, cotrimaxosol, metronidazole. Antifungal. Antiviral. Spectrum of antimicrobial activity. Principles of choice (empirical and etiotropic), determination of the dosage regimen depending on the localization of infection and severity of the condition, kidney function. Methods for evaluating the effectiveness and safety of antimicrobial drugs. Diagnostics and prevention of NLR. A combination of antimicrobial drugs and interactions when co-administered with drugs of other groups. Clinical and pharmacological approaches, taking into account nosology, individual characteristics of pharmacokinetics and pharmacodynamics, to the choice of antifungal and antiviral drugs.<br>Clinical pharmacology of psychotropic drugs. Psychostimulants are Nootropics . Anxiolytics. Neuroleptics. Anticonvulsant medications. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for mental and neurological diseases: sleep disorders, neuroses, depression, schizophrenia, manic-depressive psychosis, epilepsy, migraine, multiple sclerosis, Parkinson's disease, transient disorders of cerebral circulation (according to ischemic or hemorrhagic types). Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with the combined administration of drugs and in combination with other drugs.<br>Clinical pharmacology of drugs affecting hemostasis. Antiplatelet agents. Direct anticoagulants. Indirect anticoagulants. Fibrinolytics. Synthetic selective inhibitor of activated factor X (Xa) Drugs that increase blood clotting. Fibrinolysis inhibitors. Iron preparations. | Choose an effective, safe drug in accordance with a clinical diagnosis of standards-based pharmacotherapy of vital and essential drugs list,<br>the formulary system; calculate the load and the maintenance dose medicines; to calculate the dose of drugs for patients with chronic renal insufficiency, impaired liver function, elderly and senile age; choose pharmaceutical form of the drug, the dose, the way, the multiplicity and duration of administration, to determine the optimal dosing regimen for a specific patient; develop a program for monitoring the effectiveness and safety of prescribed medicines, choosing the necessary set of routine (survey, examination) and special laboratory and functional research methods, including therapeutic drug monitoring and study of quality of | The algorithm for choosing the drug, dosage form and dosage regimen depending on the clinical situation |

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| | | | | life indicators, in order to assess the pharmacodynamic effects of drugs, their pharmacokinetic indicators; interpret the data obtained; choose methods for adequate control of the effectiveness and safety of treatment and predict the risk of developing NLR; identify, classify, register NLR when prescribing the most common medicines and suggest ways to prevent and correct them; fill out documents on notification of the development of undesirable drug reactions; conduct | |

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| | | | Means to stop bleeding. Principles of selection and determination of the dosage regimen depending on the state of the coagulating, anti-clotting, fibrinolytic system of the patient, data on the pharmacodynamics and pharmacokinetics of drugs and their efficacy in diseases of the liver, kidneys, gastrointestinal tract, hematopoietic organs, cardiovascular system, use in various periods of pregnancy, in lactating women and the elderly (taking into account treatment standards and the list of VED). Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of steroid anti-inflammatory drugs. Clinical pharmacology of drugs affecting bronchial patency. Anti-inflammatory anti-asthmatic agents: inhaled glucocorticoids, systemic glucocorticoids. Stabilizers of mast cell membranes, leukotriene inhibitors. Antitussive and expectorant agents. Antihistamines. Pulmonary surfactants. Principles of drug selection, determination of routes of administration, methods of drug delivery to the respiratory tract and rational dosage regimen of drugs, taking into account the reversibility of airway obstruction, severity of bronchial obstruction, sputum characteristics, cardiovascular system, pharmacokinetics, factors that change sensitivity to the drug, treatment standards and the list of VED. The concept of step-by-step therapy of bronchial asthma. Diagnosis, correction and prevention of NLR. The syndrome of decreased receptor sensitivity (tachyphylaxis, internalization and decreased regulation), causing the development of resistance to beta-stimulants, methods of its correction and prevention. Methods for evaluating effectiveness and safety. Assessment of the quality of life. The concept of compliance (or adherence to treatment). Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of nonsteroidal anti-inflammatory drugs. Clinical pharmacology of cytostatics and immunosuppressants. Anti-inflammatory drugs: NSAIDs, basic, slow-acting anti-inflammatory drugs. Remedies used for gout. Drugs that affect the structure and mineralization of bones. Painkillers (paracetamol, tramadol), opioids (morphine), ketamine, fentanyl. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for rheumatic diseases: systemic lupus erythematosus, rheumatoid arthritis, deforming osteoarthritis, osteoporosis, gout. Principles of the choice of routes of administration, dosage regimen depending on features of the inflammatory process: localization, intensity, taking into account chronopharmacology. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups. | measures to increase the patient's adherence to medication; to diagnose and treat drug overdose | |

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| | | | Clinical pharmacology of drugs affecting the organs of the digestive system. Antacids. Blockers of H2-histamine receptors. Proton pump inhibitors. Prokinetics. Drugs for the treatment of functional disorders of the intestine. Enzyme preparations. pancreatin. Drugs used for diarrhea: loperamide. Laxatives. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, pharmacotherapy standards in gastroenterology and the list of VED, to the selection and use of medicines for diseases of the digestive system: gastro-esophageal reflux disease, gastric ulcer and duodenal ulcer, liver cirrhosis, chronic pancreatitis, constipation and diarrhea, irritable bowel syndrome, ulcerative colitis and disease Crown. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of drugs affecting vascular tone and hypolipidemic agents. Medications that lower vascular tone: agonists of central a2-adrenergic receptors and I1- imidazoline receptors, alpha-blockers, ACE inhibitors, angiotensin receptor antagonists, direct renin inhibitor, beta-blockers, slow calcium channel blockers, venous dilators, pentoxifylline. Hypolipidemic drugs: statins, fibrates. Fibrinolytics. Painkillers: NSAIDs, tramodol, opioids. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for coronary artery disease (angina pectoris, myocardial infarction, unstable angina), hyperlipidemia and hypertension. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.<br>Clinical pharmacology of drugs affecting the main functions of the myocardium and diuretics. Antiarrhythmic drugs. Inotropic drugs: Diuretics. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for frequent and life-threatening rhythm disorders and chronic heart failure. Methods efficiency and safety assessments. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups. | | |

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| | | | Clinical pharmacology of drugs used in endocrinology. Antidiabetic drugs. Thyroid hormone preparations and antithyroid drugs. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for type 1 and 2 diabetes mellitus, hypothyroidism, hyperthyroidism. Therapy of emergency conditions in endocrinology. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups. | | |
| 5. | OPK-8 | Evidence-based medicine. Requirements for pharmacotherapy and drug provision according to the Priority national project "Health". | Preclinical studies. Clinical drug trials: phases of clinical trials, the concept of GCP, ethical and legal norms of clinical trials, participants in clinical trials, clinical trial protocol. The concept of randomized controlled trials. Bioequivalence studies. Generics.<br>Evidence-based medicine: principles, levels (classes) evidence. The "endpoints" of clinical trials. Meta-analysis. The importance of evidence-based medicine in clinical practice. Formulary system: principles of construction, methods of selection of medicines.<br>The system of rational use of medicines in Russia. Federal and territorial lists of vital and essential medicines (VED). Formulary lists of hospitals. Protocols for the management of patients. Standards of diagnosis and treatment. Federal Guidelines for the Use of Medicines (formulary system). Clinical recommendations for pharmacotherapy of diseases of internal organs. The analog replacement form. Sources of clinical and pharmacological information (reference books, electronic databases, Internet resources). Clinical pharmacoepidemiology. Tasks, methods and types of pharmacoepidemiological studies.<br>Clinical pharmacoeconomics. Criteria of pharmacoeconomical research. Assessment of the cost of drug treatment (cost estimation). Types of pharmacoeconomical analysis.<br>Federal Law "On Circulation of Medicines". The role of the Ministry of Health and Social Development of the Russian Federation in the field of circulation of medicines. Organization of clinical and pharmacological service in the Russian Federation. Clinical and pharmacological service of medical institutions (principles of organization, main functions). Organization of work with medical devices and rules for their storage. Goals and objectives of the Priority National Project "Health". The principle of choosing rational pharmacotherapy in the work of doctors providing primary health care to the population. The program of additional drug provision. Fundamentals of anti-doping legislation. | To justify the need to include drugs in the formulary list | Methodology of planning and conducting CI medicines |

## 3. The place of discipline in the structure of the educational program

The discipline "Clinical pharmacology" refers to the basic part of Block 1 of the Federal State Educational Standard in the specialty 31.05.01 "Medical business".

## 4. The scope of the discipline

| No. n/a | Type of work | | Total credits | Total hours | Term |
|---|---|---|---|---|---|
| | | | | | XI |
| | | | | | hours |
| 1 | 2 | | 3 | 4 | |
| **1** | **Contact work of students with the teacher (total), including:** | | **2** | **72** | **72** |
| 2 | Lectures (L) | | - | 20 | 20 |
| 3 | Clinical Practical training (PZ) | | - | 52 | 52 |
| 4 | Seminars (C) | | - | - | - |
| 5 | Laboratory work (LR) | | - | - | - |
| **6** | **Independent work of a student (SRS)** | | **1** | **36** | **36** |
| **7** | **Type of intermediate certification** | credit (H) | | | + |
| | | exam (E) | | - | - |
| **8** | total: Total labor intensity | hours | | **108** | **108** |
| | | ZE | **3** | | **3** |

## 5. Content of the discipline

| № № | Semester No. | Name of the section of the academic discipline (module) | Types of educational activities, including independent work of students (in hours) | | | | Forms of ongoing monitoring of academic performance *(by semester weeks)* |
|---|---|---|---|---|---|---|---|
| | | | L | PZ | SRS | in total | |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| 1 | XI | General questions of clinical pharmacology | 14 | - | 7 | 21 | TK, SZ, UZ |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 2 | XI | Clinical and pharmacological approaches to the selection and use of medicines for diseases of internal organs. | - | 34 | 17 | 51 | TK, SZ, UZ |
| 3 | XI | Evidence-based medicine. Requirements for pharmacotherapy and drug provision according to the Priority national project "Health". | 6 | 18 | 12 | 36 | TK, SZ, UZ |
| | | **total:** | 20 | 52 | 36 | 108 | |

**Note:** C - interview, TK - test tasks, SZ - situational tasks, UZ - training tasks

**6. The list of educational and methodological support for independent work of students in the discipline**

| **No./ n** | **№ semester** | **Name of the educational and methodological development** |
|---|---|---|
| **1** | 11 | Bolieva L.Z., Gonobobleva T.N., Archegova E.G., Filippova Yu.A. Nonsteroidal anti-inflammatory drugs // Textbook - Vladikavkaz.- 2015.- 80 p.- UMO No. 47/05.05-21 of 28.09.2015 |

**7. Fund of evaluation funds for the interim certification of students in the discipline**

| **No./ n** | **List of competencies** | **№ semester** | **Evaluation indicator(s)** | **Evaluation criterion(s)** | **Rating scale** | **Name of the FOS** |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| 1 | OPK-1 OPK-5 OPK-6 OPK-7 OPK-8 | 11 | cm. the standard for assessing the quality of education, approved. By order of the FGBOU IN SOGMA Ministry of Health of Russia dated 10.07.2018., No.264/o | cm. the standard for assessing the quality of education, approved. By order of the FGBOU IN SOGMA Ministry of Health of Russia dated 10.07.2018., No.264/o | cm. the standard for assessing the quality of education, approved. By order of the FGBOU IN SOGMA Ministry of Health of Russia dated 10.07.2018., No.264/o | Test tickets; Test tasks; Control tasks |

**8. The list of basic and additional educational literature necessary for the development of the discipline**

**Basic literature**

| № | Name | Author(s) | Year, place of publication | Number of instances | | Name of the EBS |
|---|---|---|---|---|---|---|
| | | | | in the library | At the department | Name of the EBS/link to the EBS |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1. | Clinical pharmacology: textbook. | V.G. Kukes | M.: GEOTAR-Media, 2006<br>2008<br>2013<br>2015 | 104<br>28<br>9<br>102 | | "Student Consultant" http://www.studmedlib.ru/book/ISBN9785970441961.html |

**Additional literature**

| No./n | Name | Author(s) | Year, place of publication | Number of instances | | Name of the EBS |
|---|---|---|---|---|---|---|
| | | | | in the library | at the department | Name of the EBS/link to the EBS |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1. | Clinical Pharmacology: National<br>guide. | Yu.B. Belousov, V.G. Kukes, V.K. Lepakhin, V.I. Petrov | M.: GEOTAR - Media, 2009 | - | 1 | - |
| 2. | Modern antimicrobial chemotherapy:<br>a guide for doctors | Kozlov S.N., Strachunsky L.S. | M.: MIA, 2017 | - | 1 | |
| 3. | Clinical pharmacology and pharmacotherapy in real medical practice practice: textbook | Petrov V.I. | M.: GEOTAR - Media, 2015 | 3 | - | "Student Consultant" http://www.studmedlib.ru/book/ISBN9785970420331.html |
| 4. | Rational antimicrobial pharmacotherapy: a guide for practitioners | Yakovlev V.P. | M.: Litterra, 2007 | 2 | - | |

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| | doctors | | | | | |

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| 5 | Nonsteroidal anti-inflammatory drugs: a textbook | Bolieva L.Z., Gonobobleva T.N., Archegova E.G., Filippova Yu.A. | Vladikavkaz, 2015 | - | 1 | |
| 6 | Antiallergic drugs: study guide. | Bolieva L.Z. | Vladikavkaz, 2007 | 30 | 1 | EB SOGMA |
| 7 | Treatment of allergic rhinitis: a textbook. | Bolieva L.Z., Gappoeva E.T. | Vladikavkaz, 2007 | 28 | 1 | EB SOGMA |

**9. The list of resources of the information and telecommunication network "Internet", necessary for the development of the discipline**

**1. Interregional Society of Evidence-based Medicine Specialists.**
http://www.osdm.org/index.php
**2. Moscow Center for Evidence-Based Medicine**
http://evbmed.fbm.msu.ru/
**3. Databases, information and reference and search engines:**
- Standards of medical care: http://www.rspor.ru/index.php?mod1=standarts3&mod2=db1
- Protocols for the management of patients: http://www.rspor.ru/index.php?mod1=protocols3&mod2=db1
- State Register of Medicines:
http://www.drugreg.ru/Bases/WebReestrQuery.asp
- Federal State University Scientific Center for Expertise of Medical Devices of Roszdravnadzor. Circulation of medicines: http://www.regmed.ru
- Pharmaceutical Information Foundation: http://www.drugreg.ru
- Russian Encyclopedia of Medicines (Radar): http://www.rlsnet.ru
- The Vidal Handbook. Medicines in Russia: http://www.vidal.ru
- Website of the Chief Freelance Specialist - Clinical Pharmacologist of the Ministry of Health and Social Development of the Russian Federation - http://www.clinpharmrussia.ru
- Moscow Center for Evidence-Based Medicine. http://evbmed.fbm.msu.ru/
- Website "Formular system of Russia». http://www.formular.ru
- Interregional Association for Clinical Microbiology and Antimicrobial Chemotherapy (MCMAH). http://antibiotic.ru/iacmac/
- Chelyabinsk Regional Center for the Study of Side Effects of Drugs with programs for pharmacoeconomical analysis (ABC VEN analysis) and for the evaluation of drug interactions. http://tabletka.umi.ru
- Website of the program for clinical pharmacologists: http://pharmsuite.ru/
- European Society of Clinical Pharmacologists and Pharmacotherapists.
http://www.eacpt.org
- American Society of Clinical Pharmacologists and Pharmacotherapists.
http://www.ascpt.org/
- U.S. Food and Drug Administration (FDA). http://www.fda.gov
- A resource on pharmacogenetics. http://www.pharmgkb.org/
- Australian Bulletin of Adverse Drug Reactions.
http://www.tga.health.gov.au/adr/aadrb.htm
- British Monthly Bulletin on Drug Safety.
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm

- Resource on drug interaction. http://medicine.iupui.edu/flockhart/
- Lectures for postgraduate education "Principles of clinical Pharmacology" of the Clinical Center of the National Institutes of Health of the USA.
http://www.cc.nih.gov/researchers/training/principles.shtml

**4. Electronic versions of magazines:**

«Consilium medicum» - http://www.consilium-medicum.com/media/consilium
«Bulletin of Evidence-based Medicine» http://www.evidence-update.ru/
«Doctor» - http://www.rusvrach.ru/jornals/vrach
«Hematology and transfusiology» - http://www.medlit.ru/medrus/gemat.htm
«Evidence-based cardiology» - http://www.mediasphera.ru/journals/dokcard
«Intensive care» - http://www.icj.ru
«Infections and antimicrobial therapy» -
http://www.consilium-medicum.com/media/infektion/index.shtml
«Problems of endocrinology» - http://www.medlit.ru/medrus/probe.htm
«Psychiatry and psychopharmacotherapy» - http://www.consilium-medicum.com/media/psycho
«Pulmonology» - http://www.consilium-medicum.com/media/pulmo
«Russian Journal of Gastroenterology, Hepatology, Coloproctology» - http://www.m-vesti.ru/rggk/rggk.html
«Russian Medical Journal» - http://www.rmj.ru
«Modern oncology» - http://www.consilium-medicum.com/media/onkology
«Directory of polyclinic doctor» - - http://www.consilium-medicum.com/media/refer
«Difficult patient» - http://www.t-pacient.ru
«Pharmateca» - http://www.pharmateca.ru

**10. Methodological guidelines for students on the development of the discipline**

Training consists of contact work of students with a teacher (72 hours), including a lecture course (20 hours) and practical classes (52 hours), and independent work (36 hours). In accordance with the requirements of the Federal State Educational Standard, the implementation of the competence approach should provide for the widespread use of active and interactive forms of classes in the educational process (computer simulations, business and role-playing games, analysis of specific situations, psychological and other trainings) in combination with extracurricular work in order to form and develop professional skills of students. As part of the study of clinical pharmacology, meetings with representatives of Russian and foreign companies, state and public organizations, master classes of experts and specialists should be provided.

The proportion of classes conducted in interactive forms is determined by the main purpose (mission) of the program, the peculiarity of the contingent of students and the content of the discipline, and in general, in the educational process they should make up at least 10% of classroom classes (determined by the requirements of the Federal State Educational Standard, taking into account the specifics of the PLO). Lecture-type classes for the relevant groups of students cannot make up more than 30% of classroom classes (determined by the relevant Federal State Educational Standard).

Forms of work that form students' general cultural competencies:

- The student's work in the group forms a sense of collectivism and sociability.
- Independent work with patients contributes to the formation of deontological behavior, accuracy, discipline.
- Independent work with literature, writing case histories and writing and defending abstracts, receiving patients form the ability to analyze medical and social problems, the ability to use natural science, biomedical and clinical sciences in practice in various types of professional and social activities.
- Various types of academic work, including independent work of a student (writing and defending a medical history), contribute to mastering the culture of thinking, the ability to logically formalize its results in written and oral speech; readiness for

formation of a systematic approach to the analysis of medical information, perception of innovations; form the ability and readiness for self-improvement, self-realization, personal and subject reflection.
- Various types of educational activities form the ability in the conditions of the development of science and practice to re-evaluate the accumulated experience, analyze their capabilities, the ability to acquire new knowledge, use various forms of education, information and educational technologies
The main means of ensuring the development of clinical pharmacology: demonstration of patients with various diseases of internal organs, demonstration of research methods, screening of films, slides, slides, tables, posters, multimedia presentations.
The most important stage in the formation of professional competencies, the formation of stable practical skills in clinical pharmacology is the student's independent work, which consists in writing and defending a medical history.

**11. The list of information technologies used in the implementation of the educational process in the discipline**

| Term | Type of occupation L, PR,S, | Educational technologies used (active, interactive) | Number of hours | % of classes in an interactive form | List of software |
|---|---|---|---|---|---|
| 11 | L | A set of slides, videos for a traditional lecture | 20 | | Microsoft Office PowerPoint; Internet Exploer |
| 11 | PZ | A set of questions and tasks for a practical task, a set of situational tasks for a PO, a set of case histories for the analysis of clinical cases. | 52 | 20 | Microsoft Office |
| 11 | C | A set of questions and tasks for independent work | 36 | | Microsoft Office |

**12. Description of the material and technical base necessary for the implementation of the educational process in the discipline**

| **No./ n** | **Name of the equipment** | **Quantity** | **Technical condition** |
|---|---|---|---|
| **1** | **2** | **3** | **4** |
| **Special equipment** | | | |
| 1. | Computer | 4 | 2 – satisfactory |

| | | | |
|---|---|---|---|
| | | | 2 – for debiting |
| 2. | A laptop | 4 | 4 – satisfactory |
| 3. | Projector | 2 | 1 – satisfactory<br>1 – requires repair |
| 4. | Copying equipment: scanner, copier, printer | 5 | 5– satisfactory |
| 5. | Uninterruptible power supply | 2 | For debiting |
| **Tables** | | | |
| 6. | Thematic tables | 12 | 4 - need to be replaced |

## 13. Conducting educational activities using e-learning and distance learning technologies

In the conditions of the introduction of restrictive measures (quarantine) associated with an unfavorable epidemiological situation, the threat of the spread of a new coronavirus infection and other force majeure events that do not allow for face-to-face training, it is possible to study this discipline or part of it using e-learning and distance learning technologies.

Teaching the discipline in the situations described above will be carried out through the development of an electronic course with access to video lectures and interactive course materials: presentations, articles, additional materials, tests and various tasks. When conducting training sessions, ongoing monitoring of academic performance, as well as intermediate certification of students, the platforms of the electronic information and educational environment of the academy and / or other e-learning systems recommended for use at the academy can be used, such as Moodle, Zoom, Webinar et al .

Lectures can be presented in the form of audio, video files, "live lectures", etc. Conducting seminars and practical classes is possible on-line as in synchronous and asynchronous mode. Seminars can be held in the form of web conferences.