Ministry of Health of the Russian Federation

federal state budgetary educational institution
higher education
"North-Western State Medical University named after I.I. Mechnikov"

Ministry of Health of the Russian Federation

(Federal State Budgetary Educational Institution of Higher Education North-Western State Medical University named after I.I. Mechnikov of the Ministry of Health of the Russian Federation)

DISCIPLINE WORK PROGRAM

"Clinical Pharmacology"

Specialty: 31.05.01 General Medicine

Specialization: Organization and provision of primary health care to the adult population in medical organizations

Implementation language: Russian, English

2021

Подлинник электронного документа, подписанного ЭП, хранится в системе электронного документооборота ФГБОУ ВО СЗГМУ им. И.И.Мечникова Минздрава России
СВЕДЕНИЯ О СЕРТИФИКАТЕ ЭП
Сертификат 00CDEE3BD65A19B375D4FAEE2ABC26F298
Владелец Сайганов Сергей Анатольевич
Действителен с 03.12.2025 12:23:25 по 26.02.2027 12:23:25

The work program for the discipline "Clinical Pharmacology" has been developed in accordance with the Federal State Educational Standard of Higher Education (specialist degree) for Specialty 31.05.01 General Medicine, approved by Order No. 988 of the Ministry of Science and Higher Education of the Russian Federation dated August 12, 2020, "On Approval of the Federal State Educational Standard of Higher Education (Specialist Degree) for Specialty 31.05.01 General Medicine."

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The work program of the discipline was discussed at a department meeting
Internal Medicine, Clinical Pharmacology and Nephrology
April 27, 2021. Protocol No. 21,

Head of Department _____ /N.V. Bakulina/Место для ввода текста.
(signature)

Approved by the Methodological Commission for the specialty 31.05.01 General Medicine
May 11, 2021

Chairman _____ / Bakulin I.G./
(signature)

Reviewed by the Methodological Council and recommended for approval by the Academic Council
May 20, 2021

Chairman _____ / Artyushkin S.A. /
(signature)

Date of update:

CONTENTS

1.The purpose of mastering the discipline4 4
2. The place of discipline in the structure of the educational program4 4
3.List of planned learning outcomes in the discipline, correlated with the planned results of mastering the educational program4 4
4. Discipline workload and types of academic work 10 7
5. Discipline content structured by sections (topics), with the number of academic hours and types of classes indicated 10 7
6. Methodological guidelines for students on mastering the discipline 17 11
7. Assessment materials 18 11
8. Educational literature and Internet resources required for mastering the discipline 18 11
9. Information technologies used in mastering the discipline, including software, professional databases, and reference systems 19 12
10. Facilities and technical resources for the discipline 21 14
Appendix A 22 16

1. The purpose of mastering the discipline

The purpose of mastering the discipline "Clinical Pharmacology" is to develop students' competencies in selecting effective and safe medicines and dosage regimens based on clinical guidelines, diagnostic and treatment standards, formularies, and the list of vital and essential medicines for current individualized and controlled pharmacotherapy. This includes the use of core pharmacokinetic, pharmacodynamic, pharmacogenetic, pharmacoeconomic, and pharmacoepidemiological data; information on drug interactions and adverse drug reactions; and the principles of evidence-based medicine.

2. The place of discipline in the structure of the educational program

The discipline "Clinical Pharmacology" belongs to the mandatory part of Block 1 "Disciplines (Modules)" of the main professional educational program for Specialty 31.05.01 General Medicine (specialist degree), specialization: Organization and Provision of Primary Healthcare to the Adult Population in Medical Organizations. The discipline is mandatory.

3. List of planned learning outcomes in the discipline, correlated with the planned results of mastering the educational program

Code and name of competency	Code and name of the competency achievement indicator
GPC-7. Able to prescribe treatment and monitor its efficacy and safety	ID-1 GPC-7.1. Prescribes a therapeutic and protective regimen and selects the setting and type of treatment with due regard to the severity of the patient's condition ID-2 GPC-7.2. Selects medicines, dosage forms, routes of administration, and rational substitutions with due regard to the patient's condition ID-3 GPC-7.3. Predicts and prevents adverse effects of medicines ID-4 GPC-7.4. Monitors the efficacy and safety of prescribed treatment at every stage
GPC-11. Able to prepare and use scientific, research-and-production, project, organizational, administrative, and regulatory documentation in the healthcare system	GPC-11.2. Uses scientific, research-and-production, project, organizational, administrative, and regulatory documentation in professional practice
PC-3. Able to manage and treat patients requiring medical care.	ID-1 PC-3.1. Develops a treatment plan and prescribes non-pharmacological and pharmacological treatment, taking into account the diagnosis, age, and clinical presentation, in accordance with current medical-care procedures, clinical guidelines, and standards of medical care in the primary health-care setting. PC-3. Able to manage and treat patients requiring medical care ID-2 PC-3.2. Assesses the efficacy and safety of medicines, medical devices, therapeutic nutrition, and other treatment methods in primary healthcare

Competency achievement indicator code	Learning outcomes (assessment indicators)	Evaluation tools
ID-1 GPC-7.1	Knows the international classifications of diseases and medicines Standards of medical care Indications for medicines used to treat the most common diseases, with due regard to pharmacokinetic and pharmacodynamic characteristics	Security questions Test tasks Medical records Abstract
	Is able to assess a patient's condition and select the required scope and setting of pharmacotherapy Evaluate clinical guidelines, standards, and other reference sources	
	Has skills in selecting pharmacological treatment with due regard to the severity of the patient's condition and information provided in standards, clinical guidelines, and other reference sources	
ID-2 GPC-7.2	Knows standards of pharmacotherapy for the most common diseases and their complications Principles of evidence-based medicine and justification of medicine selection according to the level of evidence Major adverse effects of medicines Prognosis with different pharmacological interventions and without treatment	Security questions Test tasks Medical record Abstract
	Is able to assess a patient's condition and select the required scope of pharmacotherapy Assess the risk of adverse effects of medicines and the risk–benefit ratio Analyze the effects of medicines based on their combined pharmacological properties and their suitability for therapeutic use Formulate indications for the selected treatment method with due regard to etiotropic and pathogenetic agents; justify pharmacotherapy for an individual patient with major pathological syndromes and emergency conditions; determine the route, regimen, and dose of medicines; and assess the efficacy and safety of treatment Assess possible manifestations of medicine overdose and methods of managing them Assess the causes of changes in a patient's condition and differentiate the contribution of pharmacotherapy from other factors	
	Has skills in selecting medicines, dosage forms, routes of administration, and rational substitutions with due regard to the patient's condition; analyzing and synthesizing the medical and medication history; and predicting possible modification of the disease course and symptoms during treatment	
ID-3 GPC-7.3	Knows the classification of adverse effects of medicines Mechanisms underlying adverse effects of medicines Range of adverse effects associated with the main groups of medicines Effects of different groups of medicines on patients	Security questions Test tasks Medical record Abstract
	Is able to analyze the safety of pharmacotherapy Assess risks and monitor adverse drug reactions	

	Has skills in monitoring and actively detecting adverse drug reactions Pharmacological and non-pharmacological prevention of adverse drug reactions Treatment of adverse drug reactions	
ID-4 GPC-7.4	Knows the pharmacodynamic and pharmacokinetic characteristics of the main groups of medicines that determine their efficacy and safety profiles, and methods for assessing treatment efficacy and safety Pharmacological and non-pharmacological methods for improving treatment efficacy and safety	Security questions Test tasks Medical record Abstract
	Is able to assess the risk–benefit ratio of medicines Assess the causes of changes in a patient's condition and differentiate the contribution of pharmacotherapy from other factors	
	Has skills in prescribing maximally effective, safe, and pathogenetically justified pharmacotherapy Prescribing combination pharmacotherapy to improve treatment efficacy and minimize the risk of adverse effects	
ID-2 GPC-11.2	Knows the principal sources of professional medical information on medicines Levels of scientific evidence Content and objectives of the different phases of clinical trials of medicines.	Security questions Test tasks Medical record Abstract
	Is able to critically evaluate the results of clinical trials, standards, and guidelines	
	Has skills in finding and applying information on pharmacotherapy to provide personalized treatment, improve efficacy, and reduce the risk of adverse drug reactions	
Has skills in establishing a diagnosis in accordance with the current International Statistical Classification of Diseases and Related Health Problems (ICD).	Control questions; clinical case ID-1 PC-3.1 Knows current methods of using medicines, medical devices, and therapeutic nutrition for diseases and conditions, in accordance with current procedures for medical care, clinical guidelines (treatment protocols), and standards of care. - mechanisms of action of medicines; - indications and contraindications for their use	Security questions Test tasks Medical record Abstract
	Test tasks Prepare a treatment plan for diseases and conditions with due regard to diagnosis, age, and clinical presentation Is able to use medical devices in accordance with current procedures for medical care, clinical guidelines (treatment protocols), and standards of care. Prepare a treatment plan for diseases and conditions, taking account of the diagnosis, age, and clinical presentation	
	Has skills in prescribing medicines and non-pharmacological treatment with due regard to diagnosis, age, and clinical presentation	
Clinical case.	Knows the mechanisms of action, pharmacokinetics, pharmacodynamics, indications, contraindications, and complications of medicines used to treat major diseases	Security questions Test tasks Medical record Abstract
	Is able to assess the efficacy and safety of pharmacotherapy Improve the efficacy and minimize the risks of pharmacotherapy	
	Has skills in assessing the efficacy and safety of medicines Monitoring and reducing the risk of adverse drug reactions	

Security questions	Knows current approaches to personalized therapy for diseases and conditions, including in pregnant women and elderly and senile patients	Security questions Test tasks Medical record Abstract
	Is able to prescribe medicines with due regard to age, comorbid conditions, and diseases, in accordance with current procedures for medical care and clinical guidelines (treatment protocols)	
	Has skills in selecting personalized treatment, including the use of pharmacogenetic analysis, and choosing an effective and safe therapeutic option	

4. Scope of discipline and types of academic work

Type of educational work	Labor intensity	Semesters	
		IX	X
Contact work between students and teachers	**72**	**36**	**36**
Classroom work:	70	36	34
Lectures (L)	24	12	12
Practical exercises (PP)	46	24	22
Independent work:	**36**	**18**	**18**
during the period of theoretical training	32	18	14
preparation for the test	4	0	4
Intermediate assessment: test, including delivery and group consultations	2		2
Total workload: academic hours	**108**		
credit units	**3**		

5. The content of the discipline, structured by sections (topics) indicating the number of academic hours and types of training sessions

5.1.Content of discipline sections

item no.	Name of discipline section	Annotated content of the discipline section	List of competencies formed in the process of mastering the section
	General principles of clinical pharmacology	This section covers general clinical pharmacology, including pharmacodynamics, pharmacokinetics, pharmacogenetics, pharmacoeconomics, and related topics.	GPC-11
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	This section covers specific issues in clinical pharmacology, including pharmacotherapy of the most important diseases of the cardiovascular, respiratory, digestive, nervous, and genitourinary systems.	GPC-7, PC-3

5.2.Thematic plan of lectures

item no.	Name of discipline section	Lecture topics	Active learning formats*	Labor intensity (academic hours)

1.	General principles of clinical pharmacology	L.1 History and objectives of clinical pharmacology. Principles of rational pharmacotherapy.	LB	2
2.	General principles of clinical pharmacology	L.2 Adverse drug reactions.	LB	2
3.	General principles of clinical pharmacology	L.3 Drug interactions.	LB	2
4.	General principles of clinical pharmacology	L.4 Adherence to pharmacotherapy	LB	2
5.	General principles of clinical pharmacology	L.5 Pharmacokinetics.	LB	2
6.	General principles of clinical pharmacology	L.6 Preclinical and clinical studies	LB	2
7.	General principles of clinical pharmacology	L.7 Clinical pharmacology of antimicrobial medicines	LB	2
8.	General principles of clinical pharmacology	L.8 Clinical pharmacology of analgesics and glucocorticosteroids. Pharmacotherapy of chronic pain syndrome	LB	2
9.	General principles of clinical pharmacology	L.9 Pharmacogenetics	LB	2
10	General principles of clinical pharmacology	L.10 Assessment of the clinical efficacy and safety of pharmacotherapy. Efficacy and safety of pharmacotherapy in patients with renal and hepatic impairment	LB	2
11	General principles of clinical pharmacology	L.11 Pharmacoeconomics	LB	2
12	General principles of clinical pharmacology	L.12 Pharmacokinetic and pharmacodynamic characteristics of medicines in children, older adults, pregnant women, and breastfeeding women	LB	2
TOTAL:				24

LB – lecture-conversation

5.3.Thematic plan for practical classes

№ p/p	Name of discipline section	Topics of practical classes	Active forms of learning	Current control forms	Labor intensity (academic hours)
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	1 Clinical pharmacology c medicines used to treat acute and chronic heart failure.	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of	Standards of medical ca and clinical guidelines i gastroenterology Clinical pharmacology c	GD AC	Security questions Test tasks	4

№ p/p	Name of discipline section	Topics of practical classes	Active forms of learning	Current control forms	Labor intensity (academic hours)
	medicines for internal diseases	medicines used to treat coronary artery disease.			
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	3 Clinical pharmacology of medicines used to treat cardiac rhythm disorders	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	4 Clinical pharmacology of medicines affecting vascular tone	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	5 Clinical pharmacology of medicines affecting hemostasis	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 6 Clinical pharmacology of vitamins and medicines used to treat anemia	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 7 Clinical pharmacology of steroidal and non-steroidal anti-inflammatory medicines, cytostatic agents, and immunosuppressants.	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 8 Clinical pharmacology of medicines affecting bronchial patency.	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 9 Clinical pharmacology of medicines affecting the digestive system.	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 10 Clinical pharmacology of psychotropic medicines.	GD AC	Security questions Test tasks	4

№ p/p	Name of discipline section	Topics of practical classes	Active forms of learning	Current control forms	Labor intensity (academic hours)
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 11 Clinical pharmacology of antimicrobial medicines.	GD AC	Security questions Test tasks	4
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Practical class 12 Clinical pharmacology of antimicrobial medicines.	GD AC	Security questions Test tasks	2
TOTAL:					46

GD - group discussion
AS - situation analysis

5.4. Thematic plan of laboratory work is not provided

5.5. Independent work:

item no.	Name of discipline section	Types of independent work	Current control forms	Labor intensity (academic hours)
	General principles of clinical pharmacology	Working with lecture material Study of educational literature. Work with regulatory documents Preparation for interim assessment	Security questions Test tasks Abstract	18
	Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Working with lecture material Study of educational literature. Work with regulatory documents Preparation for interim assessment	Security questions Test tasks Abstract	18
			TOTAL:	36

5.6.1. List of regulatory documents:

1. Federal Law No. 323-FZ dated November 21, 2011, "On the Fundamentals of Health Protection of Citizens in the Russian Federation";
2. 1. Federal Law No. 273-FZ dated December 29, 2012, "On Education in the Russian Federation";
3. Federal Law No. 323-FZ dated November 21, 2011, "On the Fundamentals of Health Protection of Citizens in the Russian Federation";
4. Federal Law No. 326-FZ dated November 29, 2010, "On Compulsory Medical Insurance in the Russian Federation";
5. Order No. 541n of the Ministry of Health and Social Development of the Russian Federation dated July 23, 2010, "On Approval of the Unified Qualification Reference Book for Positions of Managers, Specialists, and Employees," section "Qualification Characteristics of Positions of Healthcare Workers";

6. Order No. 17n of the Ministry of Health and Social Development of the Russian Federation dated January 18, 2012, on approval of the procedure for providing medical care to adults in the fields of internal medicine and family medicine
7. Order No. 575n of the Ministry of Health of the Russian Federation dated November 2, 2012, "On Approval of the Procedure for Providing Medical Care in Clinical Pharmacology"

5.6.2. Written-report topics:

1. Classification of anemia. Diagnostic approaches.
2. Iron-deficiency anemia. Clinical pharmacology of medicines used to treat iron-deficiency anemia.
3. Aplastic and hypoplastic anemia. Vitamin B12- and folate-deficiency anemia. Clinical pharmacology of medicines used to treat aplastic, hypoplastic, vitamin B12-deficiency, and folate-deficiency anemia.
4. Avitaminosis, hypovitaminosis, and hypervitaminosis. Classifications and diagnostic approaches.
5. Classification of vitamins. Therapeutic approaches.
6. Conditions associated with vitamin D insufficiency and deficiency. Classification of vitamin D preparations.
7. Current clinical trials and meta-analyses on the efficacy and safety of vitamin therapy. Multivitamin preparations.

6. Guidelines for students on mastering the discipline

To master the sections of Clinical Pharmacology effectively, students should independently study the teaching materials available in Moodle, participate actively in discussions during practical classes, and seek advice from the instructor when necessary.

7. Evaluation materials

Assessment materials for the discipline for ongoing monitoring of progress and intermediate certification of students include examples of assessment tools (Appendix A to the work program of the discipline), procedure and assessment criteria.

8. List of educational literature and Internet resources necessary for mastering the discipline

8.1. Educational literature:

Clinical Pharmacology: National Guidelines / edited by Yu.V. Belousov, V.G. Kukes, V.K. Lepakhin, and V.I. Petrov. Moscow: GEOTAR-Media, 2014. 976 pp.
Petrov V.I. Clinical Pharmacology and Pharmacotherapy in Real-World Medical Practice. Moscow: GEOTAR-Media, 2014. 880 pp.
Sychev D.A., Dolzhenkova L.S., Prozorova V.K. Clinical Pharmacology Practicum: Study Guide / edited by V.G. Kukes. Moscow: GEOTAR-Media, 2013. 348 pp.
Zhidkov K.P. Critical Conditions. 2015. 85 pp.
Zagorodnikova K.A., Pokladova M.V., Burbello A.T. Medication Safety in Pregnancy. 2013. 67 pp.
Zakharova N.V. Clinical Pharmacology of Antibacterial and Antituberculosis Medicines. 2014. 44 pp.

Ilyashevich I.G. Use of Bronchodilators in Clinical Practice. 2015. 52 pp.
Ledovaya A.V. Clinical Pharmacology of Medicines Used to Treat Acute Heart Failure and Acute Coronary Syndrome. 2015.
Lutaenko E.A., Simanenkov V.I. Use of Ursodeoxycholic Acid in Internal Medicine Practice. 2015. 66 pp.
Simanenkov V.I., Poroshina E.G. Hepatoprotective Agents. 2013. 48 pp.
Simanenkov V.I., Poroshina E.G. Anxiolytic Agents for Psychosomatic Disorders. 2013. 52 pp.
Solovyova O.I. Probiotic Therapy in Clinical Practice. 2014. 38 pp.
Tikhonov S.V. Therapy of Gastroesophageal Reflux Disease. 2013. 62 pp.
Fedorova N.V., Zakharova N.V. Clinical Pharmacology of NSAIDs. 2014. 49 pp.
Fedorova N.V., Simanenkov V.I. Use of Vitamins During Pregnancy. 2013. 53 pp.
Clinical Pharmacology: Textbook / V.G. Kukes, D.A. Sychev et al.; edited by V.G. Kukes and D.A. Sychev. 6th revised and expanded edition. Moscow: GEOTAR-Media, 2021. 1,024 pp., illustrated. ISBN 978-5-9704-5881-5. Electronic text // Student Consultant Electronic Library System. URL: https://www.studentlibrary.ru/book/ISBN9785970458815.html

8.2. Resources of the Internet information and telecommunications network:

Name of Internet resource	Email address of the resource
Interregional Society of Evidence-Based Medicine Specialists	http://www.osdm.org/index.php
Moscow Center for Evidence-Based Medicine	http://evbmed.fbm.msu.ru
Interregional Association for Clinical Microbiology and Antimicrobial Chemotherapy (IACMAC)	http://antibiotic.ru/iacmac
European Association for Clinical Pharmacology and Therapeutics	http://www.eacpt.org
American Society for Clinical Pharmacology and Therapeutics	http://www.ascpt.org
U.S. Food and Drug Administration (FDA)	http://www.fda.gov
Pharmacogenetics resource	http://www.pharmgkb.org

9. List of information technologies used to master the discipline, including a list of software, professional databases and information reference systems

9.1. List of information technologies used in the educational process:

item no.	Name of discipline section	Information technology
	General principles of clinical pharmacology Clinical pharmacological approaches to the selection and use of medicines for internal diseases	Placement of educational materials in the electronic information and educational environment of North-Western State Medical University named after I.I. Mechnikov: https://szgmu.ru/rus/pdo/k/48

9.2. List of software used in the educational process (licensed and freely distributed software, including domestically produced):

item no.	Software product name	License validity period	Documents confirming right to use software products
licensed software			
1.	ESET NOD 32	1 year	Government contract № 07/2020
2.	MS Windows 8 MS Windows 8.1 MS Windows 10 MS Windows Server 2012 Datacenter - 2 Proc MS Windows Server 2012 R2 Datacenter - 2 Proc MS Windows Server 2016 Datacenter Core	Unlimited	State contract No. 30/2013-O; Government contract No. 399/2013-OA; Government contract No. 07/2017-EA.
3.	MS Office 2010 MS Office 2013	Unlimited	Government contract No. 30/2013-OA; Government contract No. 399/2013-OA.
4.	Academic LabVIEW Premium Suite (1 User)	Unlimited	Government contract № 02/2015
licensed software of domestic production			
1.	Anti-plagiarism	1 year	Government contract № 2409
2.	“WEBINAR (WEBINAR)” VERSION 3.0	1 year	Contract No. 347/2020-M
3.	"3KL e-learning environment"	1 year	Contract No. 348/2020-M
4.	TrueConf Enterprise	1 year	Contract No. 396/2020-EA
free software			
1.	Google Chrome	Unlimited	Open License Agreement GNU GeneralPublicLicense
2.	NVDA	Unlimited	Open License Agreement GNU GeneralPublicLicense
freely distributed software of domestic production			
1.	Moodle	Unlimited	Open License Agreement GNU GeneralPublicLicense

9.3. List of professional databases and information reference systems:

item no.	Name software product	License validity period	Documents confirming right to use software products	Mode access for disabled students and persons with limited health capabilities
1.	Consultant Plus	1 year	Agreement No. 655/2020-EA	-
2.	EBS “Student Consultant”	1 year	Contract No. 307/2020-EA	http://www.studmedlib.ru/
3.	EMB “Doctor	1 year	Contract	http://www.rosmedlib.ru/

	Consultant”		No. 281/2020-EA	
4.	EBS "Ibooks.ru/ibooks.ru"	1 year	Contract № 06/2020	https://ibooks.ru
5.	EBS “IPRBooks”	1 year	Contract No. 08/2020-ZK	http://www.iprbookshop.ru/special
6.	Electronic library system “Bukap”	1 year	Contract № 05/2020	https://www.books-up.ru/
7.	EBS "Lan Publishing House"	1 year	Contract No. 395/2020-EA	https://e.lanbook.com/

10. Material and technical support of discipline

Lecture classrooms for classes, group and individual consultations, ongoing assessment, and interim assessment, equipped with teaching equipment and technical aids: 47 Piskarevsky Prospect, Building L (Pavilion 18), St. Petersburg, North-Western State Medical University named after I.I. Mechnikov;
Equipment: chalkboard; instructor’s desk and chair; student desks and chairs.
Technical teaching aids: multimedia projector, teacher’s laptop, system unit, monitor.
Special technical teaching aids: Roger Pen (Roger personal wireless transmitter in the form of a pen), Roger MyLink (Roger Pen system signal receiver) (for students with hearing impairments); IntelliKeys (wired keyboard with Russian Braille with a matte black finish), (St. Petersburg, Piskarevsky Prospekt, 47, lit. R (building 9), room No. 18.19, Federal State Budgetary Educational Institution of Higher Education North-Western State Medical University named after I.I. Mechnikov of the Ministry of Health of the Russian Federation).

Special technical teaching aids: Roger Pen (Roger personal wireless transmitter in the form of a pen), Roger MyLink (Roger Pen system signal receiver) (for students with hearing impairments); IntelliKeys (wired keyboard with Russian Braille with a matte black finish), (St. Petersburg, Piskarevsky Prospekt, 47, lit. R (building 9), room No. 18.19, Federal State Budgetary Educational Institution of Higher Education North-Western State Medical University named after I.I. Mechnikov of the Ministry of Health of the Russian Federation).

Room 5, Pavilion 18 (Building L), North-Western State Medical University named after I.I. Mechnikov, 47 Piskarevsky Prospect
Classrooms for seminar-type classes, group and individual consultations, ongoing assessment, and interim assessment, equipped with teaching equipment and technical aids
Room 5, Pavilion 18 (Building L), North-Western State Medical University named after I.I. Mechnikov, Ministry of Health of Russia, 47 Piskarevsky Prospect

Equipment: chalkboard; instructor's desk; two-seat student desks (10);
Technical teaching aids: multimedia projector, instructor's laptop, monitor.
Room 5, Pavilion 18 (Building L), North-Western State Medical University named after I.I. Mechnikov, Ministry of Health of Russia, 47 Piskarevsky Prospect
Equipment: instructor's desk; two-seat student desks (6);
Technical teaching aids: multimedia projector, instructor's laptop, monitor.
Room 5, Pavilion 18 (Building L), North-Western State Medical University named after I.I. Mechnikov, Ministry of Health of Russia, 47 Piskarevsky Prospect
Equipment: chalkboard; instructor's desk; single-seat student desks (10);
Equipment: chalkboard; instructor's desk; two-seat student desks (5).
Room 5, Pavilion 18 (Building L), North-Western State Medical University named after I.I. Mechnikov, Ministry of Health of Russia, 47 Piskarevsky Prospect
Equipment: chalkboard; instructor's desk; two-seat student desks (5); visual aids.
Equipment: chalkboard; instructor's desk; two-seat student desks (5); visual aid (kidney model).

Room 5, Pavilion 18 (Building L), North-Western State Medical University named after I.I. Mechnikov, Ministry of Health of Russia, 47 Piskarevsky Prospect

Premises for independent work of students, equipped with computer equipment with the ability to connect to the Internet and provided with access to the electronic information and educational environment of the University: St. Petersburg, Piskarevsky Prospekt, 47, lit. AE (building 32),
aud. No. 1, lit. R (building 9), room. No. 18.19 FSBEI HE North-Western State Medical University named after. I.I. Mechnikov of the Russian Ministry of Health.

Appendix A

Ministry of Health of the Russian Federation

federal state budgetary educational institution
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Ministry of Health of the Russian Federation

(Federal State Budgetary Educational Institution of Higher Education North-Western State Medical University named after I.I. Mechnikov of the Ministry of Health of the Russian Federation)

EVALUATION MATERIALS

(for ongoing monitoring of progress and intermediate certification of students)

Specialty:	31.05.01 General medicine
Direction:	Organization and provision of primary health care to the adult population in medical organizations
Name of discipline:	Clinical Pharmacology

St. Petersburg – 2021

1. List of planned learning outcomes in the discipline

Competency achievement indicator code	Learning outcomes (assessment indicators)	Evaluation tools
ID-1 GPC-7.1	**Knows the international classifications of diseases and medicines** Standards of medical care Indications for medicines used to treat the most common diseases, with due regard to pharmacokinetic and pharmacodynamic characteristics	Security questions Test tasks Medical records Abstract
	Is able to assess a patient's condition and select the required scope and setting of pharmacotherapy Evaluate clinical guidelines, standards, and other reference sources	
	Has skills in selecting pharmacological treatment with due regard to the severity of the patient's condition and information provided in standards, clinical guidelines, and other reference sources	
ID-2 GPC-7.2	**Knows standards of pharmacotherapy for the most common diseases and their complications** Principles of evidence-based medicine and justification of medicine selection according to the level of evidence Major adverse effects of medicines Prognosis with different pharmacological interventions and without treatment	Security questions Test tasks Medical record Abstract
	Is able to assess a patient's condition and select the required scope of pharmacotherapy Assess the risk of adverse effects of medicines and the risk–benefit ratio Analyze the effects of medicines based on their combined pharmacological properties and their suitability for therapeutic use Formulate indications for the selected treatment method with due regard to etiotropic and pathogenetic agents; justify pharmacotherapy for an individual patient with major pathological syndromes and emergency conditions; determine the route, regimen, and dose of medicines; and assess the efficacy and safety of treatment Assess possible manifestations of medicine overdose and methods of managing them Assess the causes of changes in a patient's condition and differentiate the contribution of pharmacotherapy from other factors	
	Has skills in selecting medicines, dosage forms, routes of administration, and rational substitutions with due regard to the patient's condition; analyzing and synthesizing the medical and medication history; and predicting possible modification of the disease course and symptoms during treatment	
ID-3 GPC-7.3	**Knows the classification of adverse effects of medicines** Mechanisms underlying adverse effects of medicines Range of adverse effects associated with the main groups of medicines Effects of different groups of medicines on patients	Security questions Test tasks Medical record Abstract

	Is able to analyze the safety of pharmacotherapy Assess risks and monitor adverse drug reactions	
	Has skills in monitoring and actively detecting adverse drug reactions Pharmacological and non-pharmacological prevention of adverse drug reactions Treatment of adverse drug reactions	
ID-4 GPC-7.4	**Knows the pharmacodynamic and pharmacokinetic characteristics of the main groups of medicines that determine their efficacy and safety profiles, and methods for assessing treatment efficacy and safety** Pharmacological and non-pharmacological methods for improving treatment efficacy and safety	Security questions Test tasks Medical record Abstract
	Is able to assess the risk–benefit ratio of medicines Assess the causes of changes in a patient's condition and differentiate the contribution of pharmacotherapy from other factors	
	Has skills in prescribing maximally effective, safe, and pathogenetically justified pharmacotherapy Prescribing combination pharmacotherapy to improve treatment efficacy and minimize the risk of adverse effects	
ID-2 GPC-11.2	**Knows the principal sources of professional medical information on medicines** Levels of scientific evidence Content and objectives of the different phases of clinical trials of medicines.	Security questions Test tasks Medical record Abstract
	Is able to critically evaluate the results of clinical trials, standards, and guidelines	
	Has skills in finding and applying information on pharmacotherapy to provide personalized treatment, improve efficacy, and reduce the risk of adverse drug reactions	
Has skills in establishing a diagnosis in accordance with the current International Statistical Classification of Diseases and Related Health Problems (ICD).	**Control questions; clinical case** ID-1 PC-3.1 Knows current methods of using medicines, medical devices, and therapeutic nutrition for diseases and conditions, in accordance with current procedures for medical care, clinical guidelines (treatment protocols), and standards of care. - mechanisms of action of medicines; - indications and contraindications for their use	Security questions Test tasks Medical record Abstract
	Test tasks Prepare a treatment plan for diseases and conditions with due regard to diagnosis, age, and clinical presentation Is able to use medical devices in accordance with current procedures for medical care, clinical guidelines (treatment protocols), and standards of care. Prepare a treatment plan for diseases and conditions, taking account of the diagnosis, age, and clinical presentation	
	Has skills in prescribing medicines and non-pharmacological treatment with due regard to diagnosis, age, and clinical presentation	
Clinical case.	**Knows the mechanisms of action, pharmacokinetics, pharmacodynamics, indications, contraindications, and complications of medicines used to treat major diseases**	Security questions Test tasks Medical record Abstract
	Is able to assess the efficacy and safety of pharmacotherapy	

	Improve the efficacy and minimize the risks of pharmacotherapy	
	Has skills in assessing the efficacy and safety of medicines Monitoring and reducing the risk of adverse drug reactions	
Security questions	**Knows current approaches to personalized therapy for diseases and conditions, including in pregnant women and elderly and senile patients**	Security questions Test tasks Medical record Abstract
	Is able to prescribe medicines with due regard to age, comorbid conditions, and diseases, in accordance with current procedures for medical care and clinical guidelines (treatment protocols)	
	Has skills in selecting personalized treatment, including the use of pharmacogenetic analysis, and choosing an effective and safe therapeutic option	

2. Examples of assessment tools and assessment criteria for ongoing monitoring

2.1. Examples of incoming control

1. Groups of medicines affecting the hemostatic system.
2. Components of the hemostatic system.
3. Phases of blood coagulation.
4. Primary hemostasis.
5. Secondary hemostasis.
6. Laboratory parameters used to assess the hemostatic system.
7. Hypercoagulation: classifications.
8. Hypocoagulation: classification.
9. Clinical pharmacological characteristics and classification of antiplatelet agents; principal indications.
10. Clinical pharmacological characteristics and classification of direct-acting anticoagulants; principal indications.
11. Clinical pharmacological characteristics and classification of indirect anticoagulants; principal indications.
12. Clinical pharmacological characteristics and classification of fibrinolytic agents.

Evaluation criteria, grading scale pass/fail

Rating	Description
"passed"	Demonstrates a thorough understanding of the problem. All requirements for the task have been met
"not accepted"	Demonstrates a lack of understanding of the problem. Many requirements for the assignment have not been met. No answer.

2.2. Examples of test tasks:

ID-1 GPC-7.1. Question title: Question No. 1

Which medicine may be used to terminate ventricular bigeminy in a patient with severe cardiosclerosis and bradycardia (heart rate 58 beats/min)?

a. Lidocaine

b. Amiodarone

c. Propafenone
d. Talinolol

ID-2 GPC-7.2
Question name: Question No. 2
Required duration of indirect anticoagulant therapy before cardioversion, depending on the duration of an episode of atrial fibrillation or flutter:
a. 48 hours or more
b. 6–12 hours
c. 12–24 hours
d. 2–4 hours

ID-3 GPC-7.3
Question name:Question No. 3
Adverse effects of quinidine:
a. QT-interval prolongation and polymorphic ventricular tachycardia of the torsades de pointes type
b. Pulmonary toxicity
c. Thyroid dysfunction
d. Increased ventricular rate in patients with atrial fibrillation and Wolff–Parkinson–White syndrome

ID-4 GPC-7.4
Question name:Question No. 4
When prescribing cardiac glycosides to patients with obesity, it is necessary to:
a. Prescribe the dose according to the patient's ideal body weight
b. Prescribe the dose according to the patient's actual body weight
c. Increase the dose compared with that calculated from the patient's actual body weight
d. Reduce the dose compared with that calculated from the patient's ideal body weight

ID-2 GPC-11.2
Question name:Question No. 5
Which information source occupies the highest level in the hierarchy of evidence?
a. Randomized controlled clinical trials
b. Opinions of experts and expert committees
c. Case-control studies
d. Cohort studies

Has skills in establishing a diagnosis in accordance with the current International Statistical Classification of Diseases and Related Health Problems (ICD).
Question name:Question No. 6
Which medicine should be prescribed with caution to an 87-year-old patient with pneumonia and renal failure?
a. Gentamicin
b. Amoxicillin
c. Penicillin
d. Azithromycin

Clinical case.
Question name:Question No. 7
The adverse effects of NSAIDs are intensified by concomitant use of:
a. Low-dose aspirin

b. Antibacterial medicines
c. Aminophylline
d. Vitamin K

Security questions
Question name: Question No. 8
In a 78-year-old patient with renal failure receiving amikacin, which parameter should be monitored?

a. Creatinine
b. Amylase
c. Lipase
d. Albumin

Evaluation criteria, grading scale for test tasks

Rating		**Description**
"excellent"	5	Completed in full – 90%-100%
"good"	4	Not fully implemented – 80%-89%
"satisfactory"	3	Completed with deviation – 70%-79%
"unsatisfactory"	2	Partially completed – 69% or less correct answers

2.3. Examples of essay topics

ID-1 GPC-7.1. Differentiated therapy of community-acquired and hospital-acquired pneumonia

ID-2 GPC-7.2
Efficacy and safety of beta-lactam antibiotics
ID-3 GPC-7.3
Adverse effects of aminoglycoside antibiotics
ID-4 GPC-7.4
Efficacy and safety of fluoroquinolones
ID-2 GPC-11.2
Review of guidelines for the treatment of bacterial endocarditis
Has skills in establishing a diagnosis in accordance with the current International Statistical Classification of Diseases and Related Health Problems (ICD).
Initial pharmacological care for patients with sepsis
Clinical case.
Assessment of the efficacy and safety of urinary tract infection therapy
Security questions
Perioperative prophylaxis. Special considerations in pharmacotherapy during pregnancy.

Evaluation criteria, abstract grading scale

Rating		**Description**
"excellent"	5	All requirements for preparing the essay are met: the problem and its relevance are stated; different viewpoints are briefly analyzed; the student's own position is presented logically; conclusions are formulated; the topic is fully covered; length and formatting requirements are met; and additional questions are answered correctly.
"good"	4	The main requirements for the essay are met, but shortcomings are present, including inaccuracies, a lack of logical sequence, failure to meet length requirements, formatting omissions, and incomplete answers to additional questions during the presentation.

Rating		Description
"satisfactory"	3	There are substantial deviations from the essay requirements: the topic is covered only partially and factual errors are present in the content.
"unsatisfactory"	2	The topic of the abstract is not disclosed, a significant misunderstanding of the problem is revealed, or the abstract is not presented at all

2.4. Examples of review questions

ID-1 GPC-7.1. 1. Clinical pharmacology of medicines used to treat shock of different origins

2. Antibacterial therapy for community-acquired pneumonia according to disease severity.

ID-2 GPC-7.2

1. Principles of pharmacotherapy for acute coronary syndrome.
2. Antibacterial therapy in patients with acute kidney injury.

ID-3 GPC-7.3

1. Adverse effects of systemic glucocorticosteroids and preventive measures.
2. Adverse effects of anticoagulants and preventive measures.

ID-4 GPC-7.4

1. Methods for monitoring the efficacy and safety of NSAID therapy.
2. Methods for monitoring the efficacy and safety of antihypertensive therapy.

ID-2 GPC-11.2

1. Pharmacotherapy of community-acquired pneumonia in accordance with current guidelines.
2. Pharmacotherapy of arterial hypertension in accordance with current guidelines.

Has skills in establishing a diagnosis in accordance with the current International Statistical Classification of Diseases and Related Health Problems (ICD).

1. Pharmacotherapy of hypertensive crisis. Special considerations in elderly patients.
2. Medicines used to treat acute coronary syndrome.

Clinical case.

1. Assessment of the efficacy and safety of pharmacotherapy for acute cardiac rhythm disorders.
2. Assessment of the efficacy and safety of pharmacotherapy for acute and chronic heart failure.

Security questions

1. Special considerations in initial antibacterial therapy during pregnancy.
2. Specific features of primary healthcare for a patient with bronchial obstruction syndrome.

Evaluation criteria, assessment scale for control questions

Rating		Description
"excellent"	5	Knows all the educational material, understands it perfectly and has thoroughly mastered it. Gives correct, conscious and confident answers to questions (within the program). In oral answers he uses literary correct language and does not make mistakes.
"good"	4	Knows all the required educational material, understands it well and has mastered it firmly. Answers questions (within the program) without difficulty. In oral answers he uses literary language and does not make gross mistakes
"satisfactory"	3	Knows basic educational material. Answers questions (within the limits of the program) with difficulty. In oral answers, he makes mistakes when presenting the material and in constructing his speech.
"unsatisfactory"	2	Does not know most of the educational material, answers,

Rating		Description
		as a rule, only to the teacher's leading questions, hesitantly. Makes frequent and serious mistakes in oral answers

3. Current control procedure

Ongoing assessment is conducted through control questions, testing, and presentation of an essay.

4. Examples of assessment tools and assessment criteria for intermediate certification

4.1. Examples of educational medical records:

Example medical record (template)

ID-1 GPC-7.1, ID-2 GPC-7.2, ID-3 GPC-7.3, ID-4 GPC-7.4, ID-2 GPC-11.2, ID-1 PC-3.1, ID-2 PC-3.2, ID-4 PC-3.4

Patient's full name: M.A. Roshchina
Medical record number: 7250
Sex: female
Occupation: manager

II. Medical history data

Diagnosis:
Primary disease: community-acquired left-sided lower-lobe pneumonia.
Complications: Grade II respiratory failure. Left-sided hydrothorax.
Comorbidities: type 2 diabetes mellitus, subcompensated.

Medication history:
Previous pharmacotherapy: no data available.
Medicine intolerance: penicillin; type of adverse reaction: angioedema.

Laboratory and instrumental findings:

Complete blood count:
Hemoglobin: 124 g/L
Red blood cell count: 3.81 × 10^12/L
Color index: 0.98
White blood cell count: 9.5 × 10^9/L
Neutrophils:
- band neutrophils: 15%
- segmented neutrophils: 64%
Lymphocytes: 17%
Monocytes: 10%
ESR: 41 mm/h

Blood chemistry
Total protein: 62 g/L
AST: 0.13 mmol/L·h

ALT: 0.40 mmol/L·h
Alpha-amylase: 24 g/L·h
Total bilirubin: 22 μmol/L
Glucose: 7.9 mmol/L
Potassium: 3.0 mmol/L
Beta-lipoproteins: 44 units
Urea: 6.4 mmol/L

Stool analysis: fecal occult blood test negative.

Sputum microscopy
Abundant neutrophils; Gram-positive flora

Chest radiograph:
The chest radiograph shows extensive confluent infiltration in the lingular segments and at the base of the left upper lobe, together with fluid confined by the interlobar pleura and extending anteriorly to the 8th rib and posteriorly to the 5th rib. The right lung is unremarkable. The mediastinal structures are not widened. The hila are structured. The heart is not enlarged; the aorta is unfolded.
Conclusion: left-sided pleuropneumonia.

Urinalysis:
Color: yellow
Clarity: slightly cloudy
Reaction: alkaline
Specific gravity: 1.010
Protein: 0 g/L
Leukocytes: occasional per high-power field
Erythrocytes: 0
Squamous epithelial cells: occasional per high-power field
Bacteria: absent.

Evaluation Criteria

Rating		**Description**
"excellent"	5	All requirements for preparing and presenting the medical record are met: the principal classes of medicines used to treat the primary disease are fully specified; appropriate medicines, dosages, and treatment duration are selected; measures for assessing pharmacotherapy efficacy and safety are specified; potential adverse effects and their monitoring and prevention are discussed; length and formatting requirements are met; and additional questions are answered correctly.
"good"	4	Not all requirements for preparing and presenting the medical record are met: the principal medicine classes, medicine selection, dosages, treatment duration, and measures for assessing efficacy and safety contain shortcomings; potential adverse effects and their monitoring and prevention are discussed; length requirements are met; formatting contains minor shortcomings; and additional questions are answered

Rating		Description
		correctly.
"satisfactory"	3	The minimum requirements for preparing and presenting the medical record are met: only a limited range of relevant medicine classes and medicines is specified; dosages and treatment duration may be correct or incorrect; efficacy and safety assessment measures and potential adverse effects, monitoring, and prevention are addressed only minimally; length and formatting requirements are met; and additional questions are answered correctly.
"unsatisfactory"	2	The requirements for preparing and presenting the medical record are not met; a substantial misunderstanding of the problem is demonstrated, or the work is not submitted.

4.2. Examples of control questions

ID-1 GPC-7.1, ID-2 GPC-7.2, ID-3 GPC-7.3, ID-4 GPC-7.4
Antibacterial therapy in patients with acute kidney injury.
Adverse effects of systemic glucocorticosteroids and preventive measures.
ID-2 GPC-11.2
Pharmacotherapy of arterial hypertension in accordance with current guidelines.
ID-1 PC-3.1, ID-2 PC-3.2, ID-4 PC-3.4
Medicines used to treat acute coronary syndrome.
Assessment of the efficacy and safety of pharmacotherapy for acute cardiac rhythm disorders.
Specific features of primary healthcare for a patient with bronchial obstruction syndrome.

Evaluation criteria, assessment scale for control questions

Rating		Description
"excellent"	5	The solution is explained in detail, consistently, and accurately, with theoretical justification, the necessary diagrams and visual demonstrations, and correct, fluent use of terminology. Answers to additional questions are correct and clear.
"good"	4	The solution is detailed but not sufficiently logical, with isolated errors in detail and some difficulty with theoretical justification, diagrams, and visual demonstrations. Answers to additional questions are correct but insufficiently clear.
"satisfactory"	3	The explanation is incomplete and inconsistent, contains errors, and has weak theoretical justification. There are significant difficulties and errors in diagrams and visual demonstrations. Answers to additional questions are insufficiently clear and contain errors in detail.
"unsatisfactory"	2	The explanation is incomplete and inconsistent, contains major errors, and lacks theoretical justification. The student is unable to provide diagrams and visual demonstrations, or makes numerous errors. Answers to additional questions are incorrect or absent.

Final pass/fail assessment criteria

Rating	Description
"passed"	Demonstrates a thorough understanding of the problem. Knows the basic concepts within the framework of the issue under discussion, methods of study and their relationship with each other, practical problems and has an idea of promising directions for developing the issue under consideration

Rating	Description
"not passed"	Demonstrates a lack of understanding of the problem. Does not know the basic concepts, methods of study, within the framework of the issue being discussed, has no idea about the main practical problems

5. Intermediate assessment **procedure**

Intermediate assessment is conducted as a pass/fail test. The test includes presentation of the completed medical record and an interview based on control questions.