Ministry of the Health of Ukraine
Kharkov National Medical University
Department of Clinical Pharmacology and Internal Medicine

CLINICAL PHARMACOLOGY

Working notebook

For the foreign students self-work

Specialty "Dentistry"

VI medical faculty

Student's name

_____

_____

faculty_____group _____

Kharkov

2017

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Document compilers: L.R. Bobronnikova

I.I.Kniazkova
V.V.Zlatkina
V.D. Nemtsova
Y.N.Shaposhnikova
I.A.Ilchenko
A.S.Shalimova

Клінічна фармакологія. **Робочий зошит для самостійної роботи іноземних студентів IV курса стоматологічного факультету які вивчаються англійською мовою / Упоряд.:** Л.Р.Бобронніков а І.І.Князькова, В.В.Златкіна, В.Д.Немцова Ю.М.Шапошнікова,І.А.Ільченко,А.С.Шалімова. – Харків: ХНМУ, 2017. – 55 с.

Упорядники: Л.Р.Бобронніков а

І.І.Князькова
В.В. Златкіна,
В.Д.Немцова
Ю.Н.Шапошнікова,
І.А.Ільченко
А.С.Шалімова

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In order to improve the quality of learning material and students level of knowledge in preparation for the practical training on clinical pharmacology in extraclassis time the manuals in the form of a workbook for IV year foreign students speciality "Dentistry", who are trained in English, were developed.

Worksheet prepared in accordance with the program for clinical pharmacology according to the credit-modular system of training.

TABLE OF CONTENTS

Practical lesson N1

Topic 1. Subject and tasks of clinical pharmacology. The main dispositions of pharmacokinetics and pharmacodynamics. Drugs interaction, types of side effects, complication of drug therapy.
Topic 2. Clinico-pharmacological characteristics of drugs that affect vascular tone

1 LEVEL. Answer briefly in writing form:

1.**Give the definition of**:

I. ***Pharmacokinetics***– _____

_____

_____

_____

1)Absorption - _____

_____

_____

2)Bioavailability – _____

_____

_____

3)Distribution - _____

_____

4) Elimination(excretion)- _____

_____

_____

2. **Basic Pharmacokinetic Parameters (describe):**

_____

_____

_____

_____

_____

_____

_____

3.**Pharmacodynamics** - _____

_____

_____

1)Drug-drug interactions -_____

_____

_____

2)Adverse Drug Effects - _____
_____
_____

4.Basic Pharmacodinamic Parameters (describe):
_____
_____
_____
_____
_____
_____

4. **Evidence based medicine basic parameters** (describe):

- Placebo _____
_____
_____
_____
- Clinical randomize multicenter trial-_____
_____
_____
_____
_____
1) a prospective trial- _____
_____
_____
*2) a retrospective (case-control)-*_____
_____
_____
*3) a double-blind trial-*_____
_____
_____

5. **Pharmacogenetic**- _____
_____

6. Give the definition of:
1). Interaction between drugs – _____
_____
_____
a) Synergistic effect - _____
_____
_____
b) Antagonism -
_____

_____

c) Pharmacological incompatibilities - _____

_____

_____

d) Competitive antagonists - _____

_____

_____

e) Uncompetitive antagonists - _____

_____

_____

f) Pure agonists -_____

_____

_____

g)Partial agonists –_____

_____

_____

2. The factors or conditions that predispose or favour the appearance of interactions:

_____

_____

_____

_____

_____

_____

_____

_____

g) Partial agonists –_____

_____

_____

h) Adverse drug reactions- _____

_____

_____

_____

_____

3. Absorption interactions include:

_____

_____

_____

4. Transport and distribution interactions

_____

_____

_____

_____

5**.Metabolism interactions include**

_____

_____

_____

_____

6. Excretion interactions include

_____

_____
_____
_____

7. Classification of adverse drug reactions

a) Onset of event

1. _____
2. _____
3. _____

b) Severity of reaction:

1. _____
2. _____
3. _____
4. _____

c) Types of adverse drug reactions:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

d) Types of allergic reactions

1. _____
2. _____
3. _____
4. _____

8. Give the definitions to the concepts:

Antihypertensive drugs -_____
_____
_____
_____

Optimal blood pressure_____
_____
_____
_____

Target blood pressure _____
_____
_____
_____

Hypotension_____
_____
_____

Orthostatic hypotension -_____
_____
_____
_____

9.Classification of antihypertensive drugs

_____
_____
_____
_____
_____
_____

10. The ACE inhibitors contraindications:

11. The Angiotensin II receptors agonists contraindications:

12. Calcium antagonists of the dihydropyridine group adverse effects:

13.Indications for the beta-blockers in hypertension

14.Classification of diuretics

15.Contraindications for the use of beta-blockers:

_____

16.Specify the medication that can cause hypotension in a patient

_____
_____
_____
_____
_____
_____

17.Specify groups of drugs used to treat hypotension.

_____
_____
_____
_____
_____
_____
_____

Amount of incorrect answers: _____. Mark for the 1 level: _____.

2 level. Perform tests for self-control (for each questions, only one correct answer).

1. Which one of the following routes of drug administration produces the most rapid absorption?

A. Inhalation
B. Intravenous
C. Oral
D. Rectal
E. Sublingual

2. If a drug is highly bound to plasma proteins, it

A. has a large volume of distribution
B. has a high renal clearance
C. is a likely candidate for drug interactions
D. is most likely carried by alpha-glycoprotein
E. is a quaternary ammonium salt

3. Most drugs gain entry to cells by

A. passive diffusion with zero-order kinetics
B. passive diffusion with first-order kinetics
C. active transport with zero-order kinetics
D. active transport with first-order lunetics
E. passive diffusion through membrane pores

4. Which of the following is not a side effect of the cholinoreceptor blocker (Atropine)?

A. Decreased pulse
B. Urinary retention
C. Constipation
D. Mydriasis
E. Lethargy

5. **A patient with hypertension has been administered one of antihypertensive drugs. Blood pressure dropped back to normal, but the patient has developed a persistent dry cough. 6.Which of the following drugs has such a side effect?**

A Enalapril maleate
B Propranolol
C Clonidine

D Furosemide
*E*Nifedipine

7. Which of the following is not a side effect of the Vasodilator (Nifedipine)?

A. Nausea
B. Flush appearance
C. Vertigo
D. Sexual dysfunction
E. Hypotension

8. One of the major indicator of drug elimination from the human body is:

A. Effective halfbeak
B. Volume of distribution
C. Bioavailability
D. Bioequivalence
E.Highest concentration in blood

6. Which of the following is not a side effect of the Dieuretics (Loop dieuretics)?

A. Alkalosis
B. Nausea
C. Hypotension
D. Potassium deficits
E. Weakness

7.**A 74 y.o. patient has been suffering from hypertension for 20 years. He complains offrequent headache, dizziness, he takes enalapril. Objectively: accent of the SII above aorta, Ps- 68 bpm, rhythmic, P- 160/110 mm Hg. What group of hypotensive medications could be additionally prescribed under consideration of the patient's age?**

A. Thiazide diuretics
B. Loop diuretics
C. beta-adrenoreceptor blockers
D. alphaadrenoreceptor blockers
E. E.Central sympatholytics

8.A 67-year-old female patient suffering from the essential hypertension suddenly at night developed headache, dyspnea that quickly progressed to asphyxia. Objectively: the patient is pale, with sweaty forehead, AP- 210/140 mm Hg, heart rate - 120/min, auscultation revealed solitary dry rales and moist rales in the lower parts. The shins are pastose. What kind of emergency aid would be the most efficient in this case?

A. Nitroglycerin and furosemide intravenously
B. Enalapril and furosemide intravenously
C. Digoxin and nitroglycerin intravenously
D. Labetalol and furosemide intravenously
E. Nitroglycerin intravenously and capoten internally

9.What drug may cause constipation in a patient undergoing combined therapy for arterial hypertension?

A. Verapamil
B. Furosemide
C. Trimetazidine
D. Panangin
E. Acetylsalicilic acid in small dosages

10. A patient suffering from arterial hypertension and chronic bronchitis suddenly presented with dry cough and dyspnea. Body temperature remained unchanged. It is known that the patient takes captopril. These symptoms can be explained by increased generation of:

A Bradyquinine
B Angiotensin-1

C Renin
D Aldosterone
E Natriuretic peptide

1. A B C D	**3. A B C D**	**5. A B C D**	**7. A B C D**	**9. A B C D**
2. A B C D	**4. A B C D**	**6. A B C D**	**8. A B C D**	**10. A B C D**

Amount of incorrect answers: _____. Mark for the 2 level: _____.

3 level. Please solved next clinical situational tasks and write your answer:

Situational task 1.In a patient weighing 70 kg, acetaminophen has a Vd = 70 L and CL = 350 mL/min.

Calculate the approximately theelimination half-life of the drug

_____
_____
_____
_____

Situational task 2. A 60-year-old patient has essential hypertension stage II, coronary disease, bronchial asthma. After pharmacotherapy correction the patient exhibited a bronchospastic attack, intensified dyspnea.

Question:**What group of medical agents could provoked this complication?**

_____
_____

Question: **Which other side effects could be seen in this group?**

_____
_____
_____
_____

***Situational task* 3**. A 56-year-old patient suffering from essential hypertension was prescribed an inhibitor of angiotensin converting enzyme (ACE) and a potassium-sparing diuretic. **Such combination is:**

A Unreasonable because it increases risk of hyperkaliemia development
B Reasonable because it decreases risk of hyperkaliemia development
C Reasonable because it potentiates hypotensive effect of ACE inhibitor
D Unreasonable because it reduces hypotensive effect of ACE inhibitor
EUnreasonable because it increases risk of orthostatic collapse development

_____
_____

Situational task 4.During the combined pharmacotherapy a patient with peptic ulcer presented with black-coloured feces.

Question:**What drug might have caused such change?**

_____
_____

Question: **Which other side effects could be seen in this group?**

_____
_____
_____
_____

Amount of incorrect answers: _____. Mark for the 3 level: _____.

4 level. Write prescriptions for medicines:

Medication	**Prescriptions**
1. **Enalapril**	Rp: D.t.d. S.
2. **Nifedipine**	Rp: D.t.d. S.
3. **Torasemide**	Rp: D.t.d. S.
4. **Bisoprolol**	Rp: D.t.d. S.
5. Losar**tan**	Rp: D.t.d. S.

Amount of incorrect answers: _____. Mark for the 4 level: _____.

Overall mark for the class: _____ Teacher Signature:_____

Student signature: _____

Practical class N2

Topic 3.Clinico-pharmacological characteristics of antianginal and antiischemic medical agents

Topic 4.Clinico-pharmacological characteristics of drugs affecting blood clotting (antiplatelet drugs, anticoagulants, fibrinolitics,coagulants)

1 level. 1. Complete the teaching table (1-3)

Table 1

The pharmacological properties of antianginal medical agents

Group	**BP**	**Systemic vascular resistance**	**Venous tone**	**Pulmonary artery pressure**	**Heart rate**	**AV-, SA- conduction**	**Stroke volume**	**Myocardial contractility**	**Oxygen demand**	**Blood flow**		**Motility of the gastrointestinal tract**	**Bronchial tone**
										Coronary	**Cerebral**		
1. Organic nitrates													
Nitroglycerine													
Isosorbide dinitrate													
Isosorbide mononitrate													
2. β-blockers													
Non-selective β1, β2													
Selective β1													
3. Calcium antagonists													
Phenylalkylamines													
Dihydropyridines													
Benzothiazepines													
Biphenyl piperazines													
4. Inhibition of the funny channel													
Ivabradine													

Denote the effect availability: ↓ - decrease, 0 - no effect, ↑ - increase

Table 2

Indications for application of antianginal agents

Indication	**tes**	**β-blockers**	**Calcium antagonists**	**ine**

		Non-selective	Selective	Phenylalkylamines	Dihydropyridines	Benzothiazepines	Biphenyl piperazines	
Angina attacks prophylaxis								
Acute attack of angina pectoris								
Acute myocardial infarction								
Pulmonary edema								
Hypertension								
Cardiac arrhythmias: tachyarrhythmias								
Cardiac arrhythmias: bradyarrhythmias								
Cerebrovascular accident								

Indicate the effect availability: +, ++, -

Table 3

Adverse effects of antianginal agents

Side effect	Nitrates	β-blockers		Calcium antagonists			Ivabra-dine
	Nitroglycerine	Propranolol	Bisoprolol	Verapamil	Nifedipine		
Hypotension							
Orthostatic collapse							
Tachycardia							
Bradycardia							
Bronchospasm							
Heart failure							
Constipation, urinary retention							
Swelling of feet and ankles							
Headache, dizziness							
Flushing of skin							
Hypoglycemia							
Metgemoglobinemiya							
Withdrawal syndrome							
Tolerance							

Indicate the effect availability: +, ++, -

Answer briefly in writing form:

1. Classification of anticoagulants:

_____

2. Pharmacodynamics of heparin

3.Low molecular weight heparins

4.Side effects of heparin

5.Classification of antiplatelet agents

6. Mechanism of action of antiplatelet agents

7.Basic requirements for antithrombotic therapy

8.Indications for the antithrombotics prescription

9.Factors determining the effectiveness of antiplatelet therapy

10.New oral anticoagulants (NOA)

11.Classification of drugs that increase blood clotting.

The number of wrong answers: _____. Teacher's evaluation for the level 1 _____.

2 level. Perform tests for self-control (for each questions, only one correct answer)

1. **70 year old male with confirmed multi-vessel coronary vascular disease also suffers from COAD [chronic obstructive airway disease] and exertional angina. He is prescribed nifedipine for his angina, but shortly after beginning the medication complains of increased angina incidence. Choose an explanation:**

A. Nifedipine should not be used for angina.
B. Nifedipine- a calcium channel blocker, causes significant vasodilation, hypotension and reflex cardiac stimulation result in increased anginal episodes
C. Nifedipine in combination with propranolol, since propranolol would block reflex tachycardia due to nifedipine's vasodilatory effects.

2**. Antianginal drug administered by inhalation**:

A. Isosorbide dinitrate
B. Glyeryl trinitrate
C. Amyl nitrite
D. Isosorbid mononitrate

3. Symptoms associated with nitrates:

A. Bradycardia
B. Hypotension
C. Headache

D. Hypertension
E. B & C

4. Prinzmetal (variant) angina presents in a 25 year old female. Pharmacological management could include:

A. Diltiazem
B. Verapamil
C. Propranolol
D. Atenolol
E. A & B

5. Calcium channel blocker(s) most likely to affect myocardial contractility and AV conduction:

A. Diltiazem
B. Nifedipine
C. Nicardipine
D. Atenolol
E. Isosorbide dinitrate

6. What level of in diastolic blood pressure is prohibited to conduct thrombolytic therapy?

A. 90 mm Hg
B. 95 mm Hg
C. 100 mm Hg
D. 105 mm Hg
E. 110 mm Hg

7. A patient with a history of both angina and esophageal spasms is told by his physician that upon recurrence of pain, take a nitroglycerin tablet, sublingually and note what happens. When pain recurs, the patient takes the "nitro" and the pain goes away in about a minute. Reasonable analysis would suggest:

A. That the pain was due to myocardial oxygen insufficiency, relieved by the action of nitroglycerin on cardiac preload
B. That the pain is more likely due to esophageal spasm, because if it were due to the heart, relief would have taken longer
C. The test is inconclusive, since nitrates relax almost all smooth muscle terminating anginal symptoms or symptoms of esophageal spasm

8. Which of the following statements regarding enoxaparin is incorrect?

A. **S**ubcutaneous injection is rapidly absorbed
B. Do not administer in case of severe renal failure
C. Can be used when body weight is above 150 kg
D. Has a high antithrombotic activity against Xa factor
E. Has a high antiaggregant activity

9. Which of the following does not refer to absolute contraindications to thrombolytic therapy?

A. Age over 70 years
B. First trimester of pregnancy
C. Severe diabetic retinopathy
D. Hemorrhagic diathesis
E. Peptic ulcer disease

10. Principal mechanism by which sublingual nitroglycerin terminates anginal episodes in patients with advanced atherosclerotic coronary vessel disease:

A. Coronary vasodilation
B. Decreased afterload
C. Decreased preload
D. Decreased heart rate
E. Decreased contractility

1. A B C D	**3. A B C D**	**5. A B C D**	**7. A B C D**	**9. A B C D**
2. A B C D	**4. A B C D**	**6. A B C D**	**8. A B C D**	**10. A B C D**

The number of wrong answers: _____. Teacher's evaluation for the level 2 _____.

3 level. Please solved next clinical situational tasks and write your answer:

Situational task 1.A 60-year-old man comes into the office complaining of chest pains that primarily occur in the early morning and do not appear to be associated with stress or exercise. Following coronary angiography and positive Ergonovine stress-test you determine that this patient has angina pectoris as a result of coronary artery spasm.

1. **How would you treat the patient to alleviate the acute attacks when they occur ?**

_____
_____
_____
_____

2. **How would you treat chronically to prevent their reoccurrence?**

_____
_____
_____
_____
_____
_____
_____
_____

Situational task 2.A 72-year-old woman was taken to the emergency room with attacks of intense heart pain and the presence of a transient myocardial infarction without ST elevation (NSTEMI). In the history such compressive pain in the chest during exercise appeared approximately 1-2 times a day. She underwent coronary angiography and 2 stents were installed in places of critical narrowing of the coronary vessels.

Concomitant drug therapy of the patient includes atorvastatin 20 mg daily, clopidogrel 75 mg daily, aspirin 100 mg daily, carvedilol 6.25 mg twice daily. After objective examination nitroglycerin in an inhaled form for episodic admission in angina attacks was also prescribed. Two weeks after discharge from the hospital, she came for a follow-up examination. When examined complains about episodes of intense headache, heartburn, general weakness

Question: 1.*For which of the prescribed drugs are these side effects inherent?*_____
_____
_____
_____

Question2. Can be in addition to this therapy prescribed verapamil and why?

_____
_____
_____

Situational task 3. A 62-year-old male smoker with type 2 diabetes mellitus and hypertension presents with a 4-month history of exertional chest pain. Physical examination shows a blood pressure of 152/90 mm Hg, but is otherwise unremarkable. The ECG is normal, and laboratory tests show a fasting blood glucose value of 110 mg/dL, glycosylated hemoglobin 6.0%,

creatinine 1.1 mg/dL, total cholesterol 160, LDL 120, HDL 38, and triglycerides 147 mg/dL. He exercises for 8 minutes, experiences chest pain, and is found to have a 2-mm ST-segment depression in the inferolateral leads at the end of exercise.

***Question*1.What 1) other tests should you do ?**

_____
_____
_____
_____

Question2.**whatstrategies to control anginal symptoms would be most likely to be use**

_____
_____
_____
_____
_____

Situational task 4.A 72-year-old female who presented to the emergency department with history of chest pain and non-ST-segment elevation myocardial infarction (NSTEMI). Her past medical history was significant for intermittent chest pain. She underwent cardiac catheterization with placement of 2 drug eluding stents.

Her medication list included atorvastatin 20mg daily, clopidogrel 75mg daily, aspirin 162mg daily, diltiazam60mg four times a day. After examination she was started on ranolazine for symptomatic relief of NSTEM with angina. She presented 2 days after discharge with 2 syncope episodes, dizziness, constipation, and abdominal pain. BrainMRI (magnetic resonance imaging) and blood works including liver enzymes, renal function, and electrolytes all were within normal limits.

1. For which drugs are typical these side effects?

_____
_____
_____
_____

2. What concomitant medical agents are forbidden to take together with ranolazine and why?

_____
_____
_____
_____
_____
_____

The number of wrong answers: _____. Teacher's evaluation for the level 3 _____.

4 level. Write prescriptions for medicines:

Medication	Prescriptions
1. Nitroglycerin	Rp: D.t.d. S.
2. Hydralazine	Rp: D.t.d.

	S.
3. Verapamil	Rp: D.t.d. S.
4. Metoprolol	Rp: D.t.d. S.
5. Varfarin	Rp: D.t.d. S.

The number of wrong answers: _____. Teacher's evaluation for the level 4 _____.

Overall teacher's evaluation for the class: _____Signature of teacher: _____

Signature of student: _____

Practical lesson N3

Topic 5.Clinico-pharmacological characteristics of antibacterial and antimicrobial medical agents.
Topic 6.Clinico-pharmacologicalcharacteristics of anti-inflammatory drugs (steroidal and non-steroidal)

LEVEL 1. Answer briefly in writing form:

1.**Give the definition of**:

Antibacterial medications -_____

_____

_____

_____

_____

_____

***Minimum inhibitory concentration*(*MIC*) -** _____

_____

_____

The value of minimum inhibitory concentration for assigning antibacterial medications_____

_____

_____

_____

Eradication_____

_____

_____

_____

Postantibiotic effect _____

_____

_____

_____

_____

Basic requirements for the dosage regimen of antibacterial drugs _____

_____

_____

_____

_____

Drugs with a dose-dependent effect_____

_____

_____

_____

_____

Drugs with time-dependent effect_____

_____

_____

_____
_____
_____

Glucocorticoids - _____

_____

_____

Cyclooxygenase (COX) - _____

_____
_____
_____

2.Classification of NSAIDS

_____
_____
_____
_____
_____
_____
_____
_____

3. Clinical uses of NSAIDs

1. _____
2. _____
   _____
3. _____
4. _____

4. Adverse effects of NSAIDs

1)gastrointestinal
effects:_____
_____
_____
2) renal effects:_____
_____
_____
3)_____
4) central symptoms:_____
_____
5) allergic reactions:_____
_____

5.Classification of glucocorticoids:

_____
_____
_____

_____

_____

_____

6. Mechanisms of glucocorticoid action :

a) Impact on the immune system:

_____

_____

b) Effect on water and electrolyte metabolism :

_____

_____

c) Effects on metabolism :

_____

_____

d) Impact on CVS Impact on the system of the hypothalamus -pituitary- adrenal Effects on blood:

_____

_____

7. Indications for glucocorticoids:

1. _____
2. _____
3. _____
4. _____
5. _____

13. Contraindication for glucocorticoids:

1._____
2._____
3._____
4._____
5._____
6._____

Complete the teaching table (1-3)

Table 1

Classification of antibacterial agents into bactericidal and bacteriostatic

Bactericidal	**Bacteriostatic**
1.	1.
2.	2.
3.	3.
4.	4.
	5.

Table 2

Classification of antibacterial agents according to mechanism of action

Mechanism of action	Antibacterial agent
Inhibition of cell wall synthesis	1. 2. 3. 4.
Inhibition of DNA gyrase	
Inhibition of RNA polymerase	
Inhibition of protein synthesis	1. 2. 3. 4.
Inhibition of folic acid metabolism	1. 2.

Table 3

Classes of Antibiotics and their Properties (summary of the types or classes of antibiotics and their properties including their spectrum and mode of action).

Chemical class	Examples	Spectrum (effective against)	Mode of action
Example of filling			
Beta-lactams (penicillins and cephalosporins)	Penicillin G, Cephalothin	Gram-positive bacteria	Inhibits steps in cell wall (peptidoglycan) synthesis and murein assembly
Semisynthetic beta-lactams			
Clavulanic Acid			
Monobactams			
Carboxypenems			
Aminoglycosides	Streptomycin		
	Gentamicin		

Glycopeptides	Vancomycin		
Lincomycins			
Macrolides			
Polypeptides	Polymyxin		
	Bacitracin		
Polyenes	Amphotericin		
	Nystatin		
Rifamycins	Rifampicin		
Tetracyclines	Tetracycline		
Semisynthetic tetracycline	Doxycycline		
Chloramphenicol	Chloramphenicol		
Quinolones	Nalidixic acid		
Fluoroquinolones	Ciprofloxacin		

Cephalosporins			
Growth factor analogs	Sulfanilamide, Gantrisin, Trimethoprim		
	Isoniazid (INH)		
	Para-aminosalicylic acid (PAS)		

The number of wrong answers: _____. Teacher's evaluation for the level 1 _____.

2 level. Perform tests for self-control (for each questions, only one correct answer)

1. Activity COX can be inhibited with the use of some medications. Which one has the irreversible inhibitory effect on this enzyme ?

A. Norsulfazol
W. Diclofenac sodium
S. Sulfodymezyn
D. Aspirin
E. Tocopherol

2. Continious taking of a drug can result in osteoporosis, erosion of stomach mucous membrane, hypokaliemia, retention of sodium and water, reduced content of corticotropin in blood. Name this drug:

A.Prednisolone
B.Hydrochlorothiazide
C.Digoxin
D.Indometacin
E.Reserpine

3. A 31 year old man complains about dryness, burning of tongue dorsum that appeared for about a week ago and is getting worse during eating stimulating food. Some time ago the patient had pneumonia. He spent two weeks at a hospital, was taking antibiotics. He doesn't take any drugs at the moment. Objectively: mucous membrane of oral cavity is hyperemic, dry and glossy. On the tongue dorsum and palate some grayish-white films are present that can be easily removed. Threads of saliva follow the spatula. What is the most probable diagnosis?

A. Acute atrophic candidosis
B. Chronic hyperplastic candidosis
C. Chronic atrophic candidosis
D. Drug-induced stomatitis

E. Acute pseudomembranous candidosis

4. Minimal duration of antibacterial treatment usually is:

A. Not less than 1 day
B. Not less than 5 days
C. Not less than 10-14 days
D. Not less than 3 weeks

5. A patient suffering from stomach ulcer has been treated with an antacid drug almagel. For acute bronchitis treatment he was prescribed the antibiotic methacyclin e. However within next 5 days the fever didn't fall, cough and sputum nature remained unchange d. A physician came to the conclusion that the drugs were incompatibl e. What type of drug incompatibility is the case?

A. Pharmaceutic
B. Pharmacodynamic
C. Pharmacokinetic, absorption stage
D. Direct antagonism
E. Pharmacokinetic, biotransformation stage

6. An infectious patient manifests sensibilization to penicillin. Which of the following antibiotics is the safest to be applied in this case?

A. Ampicillin
B. Erythromycin
C. Oxacillin
D. Amoxicillin
E. Bicillin

7. A female patient in the first trimester of pregnancy has been diagnosed with acute pyelonephritis. What is the antibiotic drug of choice for treating this patient?

A. Norfloxacin
B. Amoxicillin
C. Amikacin
D. Chloramphenicol
E. Gentamicin

8. A 9 y.o. child has been taking antibiotics on account of bronchopneumonia for a long time. There appeared pain and burning in the area of mucous mebrane of his lips and tongue. Objectively: mucous membrane of lips and tongue has caseous and grey plaques that can be easily removed by a spatula leaving hyperemia foci on their spot. Microscopical examination of the plaques revealed mycelium. What is the most probable diagnosis?

A. Candidous cheilitis
B. Exfoliative cheilitis
C. Leukoplakia
D. Contactant allergic cheilitis
E. Manganottis cheilitis

9. Patients with asthma who regularly takes prednisone pills and inhaled formoterol due to bronchopulmonary infection were assigned erythromycin, Bromhexine and theophylline**. On the third day of treatment headache, palpitation, reduction in blood pressure, nausea and vomiting were developed. The toxic effect of which drug is associated with these symptoms?**

A. Theophylline
B. Prednisone
C. Erytromicyn
D. Formoterol
E. Bromhexine

10.A 4 years old child is for the treatment of acute tonsillitis was administrated an antibacterial drug. After 2 weeks after treatment there was the yellow color of the teeth,

which cannot be removed with toothpaste. Which antibiotic might have caused this complication?

A. Azithromycin
B. Metronidazole
C. Tetracycline
D. Ceftriaxone
E. Amikacin

1. A B C D	**3. A B C D**	**5. A B C D**	**7. A B C D**	**9. A B C D**
2. A B C D	**4. A B C D**	**6. A B C D**	**8. A B C D**	**10. A B C D**

3 level. Please solved next clinical situational tasks and write your answer:

Situational task 1.While on holiday in Spain, a 62-year-old man develops a cough, fever and breathlessness at rest. He is told that his chest x-ray confirms that he has right side segmental pneumonia. He is started on a seven-day course of oral antibiotics by a local physician and stays in his hotel for the remainder of his ten-day holiday. When he returns home, he is reviewed by his own GP who notices that he looks pale and sallow and is still breathless on exertion, but his chest examination no longer reveals any signs of pneumonia. A full blood count reveals a haemoglobin level of 6.7 g/dL (previously normal), normal white blood count and platelets, and a reticulocyte count of 4.1%.

Question: **What other tests should you do and what antibiotics would be most likely to cause this clinical scenario?**

_____
_____
_____
_____
_____
_____
_____

Situational task 2.A 53-year-old woman who has been treated for rheumatoid arthritis for a long time complains about arterial pressure rise, gastric pain, heartburn.

Question: **What preparation has she taken?**

_____
_____

Question: **What other side effects this drug can occur?**

_____
_____
_____
_____

Situational task 3.A 53-year-old woman who has been treated for rheumatoid arthritis for a long time complains about arterial pressure rise, gastric pain, heartburn.

Question: **What preparation has she taken?**

_____
_____

Question: **What other side effects this drug can occur?**

_____
_____
_____

_____

Situational task 4.A baby, aged 8 months, is examined and a diagnosis of atypical community-acquired pneumonia of chlamidial etiology is made**.**

Question: **What is the optimum alternative of antibiotics therapy in this case?**

_____

_____

_____

The number of wrong answers: _____. Teacher's evaluation for the level 3 _____.

4 level. Write prescriptions for medicines:

Medication	Prescriptions
Gatifloxacine	Rp: D.t.d. S.
Co-amoxiclav (amoxicillin/clavulanic acid)	Rp: D.t.d. S.
Azithromycin	Rp: D.t.d. S.
Ceftriaxone	Rp: D.t.d. S.
Paracetamol	Rp: D.t.d. S.
Ibuprofen	Rp: D.t.d. S
Prednisone (in tablets)	Rp: D.t.d. S

The number of wrong answers: _____. Teacher's evaluation for the level 4 _____.

Overall teacher's evaluation for the class: _____

Signature of teacher: _____

Signature of student: _____

Practical lesson N4

Topic 7. Clinico-pharmacological characteristics of local anesthetics and antiseptics
Topic 8.Clinico-pharmacologicalcharacteristics of antiallergic drugs.

1 LEVEL. Answer briefly in writing form

1. Give the definitions to terms:

1) Antigen – _____

_____

2) Antibody – _____

_____

3) Target cells – _____

_____

4) Antigen presenting cells –_____

_____

5) *Phagocytic cells* –_____

_____

6) Mediator cells –_____

_____

7) Atopy –_____

_____

2.The aim of antiallergic drugs pharmacotherapy is:

_____

_____

_____

_____

_____

3. Classification of Mast Cell Stabilizers:

_____

_____

_____

_____

_____

_____

4.Mechanism of Mast Cell Stabilizers Action*:*

_____

_____

5. Mechanismal Classification of Leukotriene Modifiers?

5. Pharmacological Actions of Leukotriene Modifiers

6. Classification of H_1-antihistamines

7. Mechanism of H_1-antihistamines Action

8. Adverse drug reactions of H_1-antihistamines

9. Clinical use of H_1-antihistamines

10. Classification of local anesthetics

11.Localanestheticsmechanism of action

12. Factors affect the reactios of local anesthetics

_____
_____
_____
_____
_____
_____

13. The local adverse effects of local anesthetic agents include:

_____
_____
_____
_____

14. The General adverse effects of local anesthetic agents include:

_____
_____
_____
_____
_____

15. Groups of antiseptics used in dental practice (with examples of the drugs):

_____
_____
_____
_____
_____
_____
_____
_____

16. Indications for antiseptics in dental practice:

_____
_____
_____
_____
_____
_____
_____
_____

Amount of incorrect aswers: _____. Mark for the 1 level: _____.

2 level.Perform tests for self-control (for each questions, only one correct answer)

1. All of the following drugs are effective for allergy Type 1, except:

A. Adrenaline
B. Aminophylline.
C. Acetylsalicylic acid.
D. Glucocorticoids.
E. Diphenhydramine.

2. For urticaria could be used:
A. antihistamines
B. Antibiotics
C. Diuretics
D. antiplatelets
E. vasodilators

3. A student came to see a doctor and asked to administer him a drug for treatment of allergic rhinitis that occurs in the period of linden flowering. What drug may be used?
A. Loratadine
B. Noradrenaline hydrotartrate
C. Propanolol
D. Ambroxol
E. Losartan

4. A 45-year-old woman suffers from allergic seasonal coryza caused by the ambrosia blossoming. What medicine from the stabilizer of the adipose cells group can be used for prevention of this disease?
A. Diazoline
B.Ketotifen
C. Phencarol
D. Tavegyl
E. Dimedrol

5. Most of the daily dose of prednisolone should be administered
A. in the evening
B. in the afternoon
C. in the morning
D. at night
E. Any time

6. A 25-year-old woman with red and itchy eczematoid dermatitis visits your office. She had a dental procedure one day earlier with administration of a local anesthetic. There were no other findings, although she indicated that she had a history of allergic reactions. Which of the following drugs is most likely involved?
A. Procaine
B. Cocaine
C. Lidocaine
D. Bupivacaine
E. Etidocaine

7. In the treatment of anaphylactic shock are used
A. corvalol, nitroglycerin
B. atropine, menadione
C. dibazol, pentamin
D. adrenaline, prednisolone
E. morphine, nitroglycerin

8. Your medical student patient suffers from troublesome allergic rhinitis due to pollen, and you want to prescribe a drug for her that is least likely to cause sedation. Your best choice would be
A. betamethasone
B. cimetidine

C. hydroxyzine
D. loratadine
E. metoclopramide

9. Before the infiltration anaesthesia a patient had been tested for sensitivity to novocaine. The reaction turned out to be positiv e. Which of the below listed drugs can be used for anaesthetization in this case?

A. Trimecaine
B. Procainamide hydrochloride
C. Anesthezin
D. Tetracaine
E. Lidocaine

10. A 22-year-old patient is afraid of pain from conduction anaesthesia. A dentist decided that this anaesthesia should be preceded by applicational anaesthesia of mucous membrane on the spot of injection. What drug should be used for this purpose?

A. 1% synthomycin ointment
B. 5% lidocaine ointment
C. 5% oxacillin ointment
D. 3% sinaflan ointment
E. 3% doxycyclin ointment

1. A B CDE	**3. A B CDE**	**5. A B CDE**	**7. A B CDE**	**9. A B CDE**
2. A B CDE	**4. A B CDE**	**6. A B C D E**	**8. A B C D E**	**10. A B C D E**

Amount of incorrect aswers: _____. Mark for the 2 level: _____.

3 level. Solve the clinical situational tasks:

***Situational task* 1**.A 16-year-old adolescent was vaccinated with DTP. In eight days there was stiffness and pain in the joints, subfebrile temperature, urticarial skin eruption, enlargement of inguinal, cervical lymph nodes and spleen.

Question:**What kind of allergic reaction is observed?**

_____

_____

Question: **What treatment have to be prescribed?**

_____

_____

_____

_____

Situational task 2.32 –years- old man visits a physician with complains of severe itching, blisters all over his body. The condition relates to the use of fish. All symptoms present 2 days. Loratadine was prescribed.

Question:**What side effects may occur in this case?**

_____

_____

_____

_____

Situational task 3. For prophylaxy allergen-induced bronchospasm 27-years old woman was prescribed Ketotifen.

Question:**What mechanisms of action of this drug make it useful in such cases?**

_____

_____

_____

Situational task 4. 15 minutes after the second vaccination with DTP vaccine a 4-month-old boy exhibited the symptoms of Quincke's edema.

Question: **What medication should be given for emergency aid?**

_____

_____

_____

_____

Question:**What is the mechanism of action of this drug in this case?**

_____

_____

_____

_____

Situational task 5. During local anesthetization (with 2 ml of 10% solution of lidocaine) a 9 year old girl cried out, lost consciousness, there appeared generalized convulsions. Objectively: the childs skin is pale and cyanoti C. It is impossible to feel the pulse because of convulsions.

Question:**What is your provisional diagnosis?**

_____

_____

Question:**What medication should be given for emergency aid?**

_____

_____

_____

Situational task 6. A patient got an injection of 0,25% novocaine solution for the purpose of anaesthetization. Suddenly the patient has presented with red spots, intense sweating, tachycardia, edema of nasal mucous membrane, bronchospasm,.

Question: **What is the cause of this complication?**

_____

_____

_____

Amount of incorrect aswers: _____. Mark for the 3 level: _____.

4 level. Prescribe the recepies:

Medication	Prescriptions
1. **Loratadine**	Rp: D.t.d.

	S.
2. **Disodium Cromoglycate**	Rp: D.t.d. S.
3. **Ketotifen**	Rp: D.t.d. S.
4.Lidocaine	Rp: D.t.d. S.
5. Bupivicaine	Rp: D.t.d. S.
6.Myramistin	Rp: D.t.d. S.

Amount of incorrect aswers: _____. Mark for the 4 level: _____.

Overall mark for the class: _____

Teacher Signature:_____

Student signature: _____

APPROXIMATE LIST OF QUESTIONS TO FINAL CONTROL

1. Classification of lipid-lowering drugs.
2. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for statins.
3. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for fibrates administration.
4. Omega 3 - fatty acids. The mechanism of action. Features of the application.
5. Classification of dyslipidemia. Differentiated approach to the use of lipid-lowering medications.
6. Group of medicines related to the anti-ischemic and antianginal drugs.
7. Mechanism of action, pharmacological effects, indications and contraindications to organic nitrates administration.
8. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications to beta - blockers.
9. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications to calcium channel blockers.
10. Classification of calcium channel blockers. Peculiarities of administration. Dosage.
11. Classification of beta-blockers. Peculiarities of administration. Dosage.
12. Antiplatelet drugs. Classification. Mechanisms of action. Methods of administration.
13. Thrombolytic agents. Indications and contraindications for thrombolysis. Schemes of administration.
14. Anticoagulants. Classification. Mechanisms of action. Side effects.
15. Classification of antihypertensive drugs.
16. Differentiated approach to antihypertensive therapy with concomitant diseases (diabetes, asthma, pregnancy, old age, pheochromocytoma, etc.).
17. The mechanism of antihypertensive action, pharmacological effects, side effects when prescribing calcium antagonists dosage.
18. The mechanism of antihypertensive action, pharmacological effects, side effects when prescribing beta -blockers. Dosage.
19. The mechanism of antihypertensive actions, pharmacological effects, indications and contraindications, side effects when prescribing angiotensin-converting enzyme inhibitor. Dosage.
20. The mechanism of antihypertensive action, pharmacological effects, indications and contraindications, side effects when prescribing angiotensin II receptor antagonists. Dosage.
21. Principles of combined use of antihypertensive drugs.
22. Classification of antiarrhythmic medicines.
23. Differentiated approach to the administration of antiarrhythmic medications.
24. Classification of cardiac glycosides. Dosage.
25. Cardiac effects of cardiac glycosides (digoxin).
26. Indications for cardiac glycosides.
27. Clinical and ECG signs of cardiac glycosides intoxication.
28. Non-glycoside inotropic agents. Indications for use.
29. Classification of diuretics.
30. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for loop diuretics.
31. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for the purpose of thiazide and to thiazides similar agents. Dosage.
32. The mechanism of action and pharmacological effects of potassium sparing diuretics. Indications and contraindications for use. Dosage.
33. A differentiated approach to the choice of diuretic agents, depending on the presence of comorbidities (effects on lipid and carbohydrate metabolism).
34. Classification of medical agents affecting the bronchial patency.

35. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for β2 agonists administration, short-acting β2 agonists. Dosage.
36. Mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for β2 agonists. Long-acting β2 agonists. Dosage.
37. Methylxanthines, mechanism of action, pharmacological effects, side effects. Dosage.
38. Glucocorticoids. Advantages of inhaled forms. Different dosing regimens.
39. Systemic adverse events occurring with prolonged use of glucocorticoids.
40. Withdrawal effects of glucocorticosteroids.
41. Antitussive agents. Mechanisms of action. Dosing regimens.
42. Drugs interaction.
43. Types of side effects.
44. Classification of NSAIDs.
45. Mechanisms of action, pharmacological properties of NSAIDs.
46. Indications and contraindications. Side effects of NSAIDs.
47. Regime of NSAIDs dosing**.**
48. The most frequent mistakes in antimicrobial drugs prescribing.
49. Allergic reactions to administration of antibacterial agents . Clinical implications.
50. Classification. The spectrum of activity. Mechanism of action . Features of the penicillins application. Dosage.
51. Classification. The spectrum of activity. Mechanism of action . Features the cephalosporins use. Dosage.
52. Classification. The spectrum of activity. Mechanism of action . The carbapenems application features. Dosage.
53. Classification. The spectrum of activity. Mechanism of action . Features of aminoglycosides use. Dosage.
54. Classification. The spectrum of activity. Mechanism of action. Features the fluoroquinolones use. Dosage.
55. Classification. The spectrum of activity. Mechanism of action. The macrolides application features. Dosage.
56. Medications that stimulate motilityof the gastrointestinal tract. Classification.
57. Mechanism of action, pharmacokinetics and pharmacodynamics , indications and contraindications for the dopamine receptors selective blockers. Dosage.
58. Clinical and pharmacological characteristics of drugs which inhibit the digestive tract motility - loperamide. Dosage.
59. Medical agents with spasmolytic activity, mechanisms of action , pharmacological properties, indications , contraindications, dosage.
60. Medical agents with anti-secretory activity.
61. Classification, mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for the purpose of proton pump inhibitors. Dosage.
62. Classification, mechanism of action, pharmacokinetics and pharmacodynamics, indications and contraindications for the use of H2-histamine receptor blockers. Dosage.
63. Antacids mechanism of action. Pharmacological properties. Dosage.
64. Cytoprotectors . Pharmacological features. Dosage.
65. Hepatoprotectors . Classification. Mechanism of action, pharmacokinetics and pharmacodynamics , indications and contraindications for use. Dosage.
66. Pancreatic enzymes. Pharmacological features. Indications for use. Side effects .Dosage .
67. Complications of drug therapy.
68. Classification, mechanism of action, pharmacokinetic and pharmacodynamic , indications and contraindications for antiallergicdrugs. Dosage .

Notes

Notes

LIST OF ALL MEDICATIONS WHICH STUDENTS OF MEDICAL AND DENTISTRY FACULTIES MUST KNOW

ANTIBACTERIAL AGENTS

1. Benzylpenicillin -sodium
2. Oxacillin – sodium
3. Ampicillin – sodium
4. Carbenicillin
5. Clarithromycin
6. Gentamycin sulfate
7. Tetracycline hydrochloride
8. Doxycycline hydrochloride
9. Erythromycin
10. Azithromycin
11. Amoxicillin
12. Clavulanicacid
13. Rovamicin
14. Diflucan / Fluconazole
15. Levofloxacin
16. Gatifloxacin
17. Moxifloxacin

ANTIVIRAL AGENTS

1. Interferon-alpha
2. Interferon-alpha (pegylated)
3. Ribavirin
4. Lamivudine
5. Rimantadine

ANTIPARASITICAGENTS

1. Quinine sulfate
2. Primaquine
3. Albendazole
4. Vermox (Mebendazole)
5. Pyrantel

NONSTEROID ANTI-INFLAMMATORY AGENTS

- Acetylsalicylic acid
- Indometacin
- Diclofenac sodium
- Ibuprofen
- Nimesulid
- Meloxicam
- Celecoxib

GLUCOCORTICOIDS

- Cortisone Acetate
- Prednisolone
- Triamcinolone
- Dexamethasone
- Budesonide
- Methylprednisolone

IMMUNOMODULATORS AND ANTIRHEUMATIC DRUGS

1. Plaquenil (Hydroxychloroquine)
2. Levamisole
3. Azathioprine (Imuran)
4. Chlorbutin
5. D-penicillamine

CARDIAC GLYCOSIDE

1. Digoxin
2. Digitoxin
2. Strophanthin
3. Corglycone

PERIPHERAL VASODILATOR

1. Nitroglycerine
2. Molsidomine
3. Nitroprusside Sodium
4. Isosorbide Dinitrate
5. Isosorbide -5-Mononitrate

ANGIOTENSIN-CONVERTINGENZYME (ACE) INHIBITORS AND ANGIOTENSIN II RECEPTOR ANTAGONISTS

2. Captopril
3. Enalapril maleate
4. Lisinopril
5. Perindopril
6. Ramipril
7. Quinapril
8. Losartan
9. Irbesaftan
10. Olmesartan
11. Telmisartan
12. Valsartan

CALCIUM CHANNEL-BLOCKING AGENT

2. Verapamil
3. Diltiazem
4. Nifedipine
5. Amlodipine
6. Nimodipine
7. Lercanidipine

HYPOLIPIDEMIC AGENTS

3. Simvastatin
4. Atorvastatin
5. Rosuvastatin
6. Lovastatin
7. Fenofibrate

MEDICINES WHICH TAKE ACTION ON ADRENERGIC SYSTEM

1. Phentolamine
2. Pyroxan
3. Moxonidine
8. Doxazosin
9. Propranolol
10. Metoprolol

4. Methyldopa
5. Dopamine
6. Dobutamine
7. Prazozine
11. Bisoprolol
12. Nibivolol
13. Carvedilol

DIURETICS

1. Hydrochlorothiazide
2. Indapamide
3. Clopamide
4. Furosemide
5. Torasemide
6. Ethacrynic acid
7. Eplerenon (inspra)
8. Diacarb
9. Spironolactone
10. Mannitol

ANTIARRHYTHMIC DRUG

1. Amiodarone
2. Dronedarone
3. Propafenone
4. Novocainamide

MEDICAL AGENTS FOR THE TREATMENT OF AIRWAY CONDUCTANCE ABNORMALITIES

4. Orciprenalin (alupent)
5. Fenoterol
6. Izadrine hydrochloride
7. Tiotropium bromide
8. Efedrin hydrochlorid
9. Comoglycate Sodium
10. NedocromilSodium
11. Ketotifen

MEDICAL AGENTS FOR THE TREATMENT OF DIGESTIVE SYSTEM DISEASES

4. Almagele
5. Bismuth subcitrats
6. Famotidine
7. Allachole
8. Flamine
9. Cholosasum
10. Chophytole
11. Ursodeoxycholic acid
12. Festale
13. Pancreatine
14. Digestal
18. Loperamide
19. Omeprazole
20. Lansoprazole
21. Rabeprazole
22. Pantoprazole
23. Esomeprazole
24. Legalon
25. Silibor
26. Bifidum-bacterin
27. Linex
28. Mebeverine

15. Plantaglucide
16. Ademethionin
17. Sodium picosulfate
29. Metoclopramide
30. Domperidone
31. Prifinium bromide
32. Ondasetron

TISSUE METABOLISM ACTIVATORS

3 Solcoseryl
4 Aktovegin
5 Pentoxifylline
6 Thiotriazoline

ANTICOAGULANT, ANTITHROMBOTIC, AND THROMBOLYTIC AGENTS

3 Ethamsylate
4 Vikasol
5 Aminocapronic acid
6 Ticlopidine
7 Streptokinase
8 Alteplase
9 Heparin
10 Nadroparin
11 Enoxaparin
12 Fraxiparine
13 Fondaparin

MEDICINES WHICH USED FOR THE TREATMENT FOR HEMOBLASTOSIS AND ANOTHER MALIGNANT TUMORS

1. Methotrexate
2. Cyclophosphane
3. Mercaptopurine
4. Fluorouracil
5. Phosphazine
6. Procarbazine hydrochloride
7. Myelosan
8. Rubomycine hydrochloride

MEDICATIONS FOR THE TREATMENT FOR PROFESSIONAL POISONING

1. Alloxim
2. Dipiroxim
3. Iisonitrozine
4. Cuprenyl
5. Sodium thiosulfate
6. Pentacin

READING LISTFOR LEARNING:

1. Goodman & Gilman's The Pharmacological Basis of Therapeutics / Laurence L. Brunton, Keith L. Parker, Donald K. Blumenthal, Iain L.O. Buxton / 11th edition/2007
2. Basic & Clinical Pharmacology / Bertram G. Katzung / 10th edition / 2006.
3. Katzung & Trevor's Pharmacology: Examination & Board Review / Trevor A.J., Katzung B.G., & Masters S.B. / 7th edition / 2005
4. USMLE Road Map: Pharmacology / Katzung B.G., Trevor A.J. / 2nd edition / 2006
5. База даних тестового контролю МОЗ України – Київ, 2013
6. Drug Facts and Comparisons. 2001 ed. St. Louis: Facts and Comparisons/ .- 2000.
7. Middleton, Elliott, Jr., et al., eds. Allergy: Principles and Practice / 5th ed. -St. Louis: Mosby.-Year Book.- 1998. 2v

CARD-NOTIFICATION FOR THE ADVERSE REACTION (AR) and/or lack of efficacy (LE) of the medical agent (MA) during its medical use	MEDICAL DOCUMENTATION Form No. 137 / o

I. GENERAL INFORMATION

1.Patient's initials	2. Number of history case/ source documentation	3. Date of birth			4. Sex	5. Consequence of AR/LO
		day	month	year		□recovery □recovers □without changes □unknown □recovery with sequelae □death not from AR □death probably from AR □death from AR

6. Onset of AR/LO(date, time) /____/____/_____/, /____/____/	7. End of AR (date,time) /____/____/_____/, /____/____/	9. Category of AR/LO
8. Description of the AR / Specification of the LO of the MA (including laboratory and instrumental research data, which relate to AR)		□patient's death /___/___/_____/ □threat to life □ hospitalisation □prolongation of hospitalization □long-term disability, disability □birth defects □another important medical event □none of the above

II. INFORMATION ABOUT SUSPICIOUS medical agent (SMA), MANUFACTURER of SMA (for vaccines additionally see the reverse side of the map)

10. SMA *(trade name, drug form)*	11. Manufacturer, country				12. Serial number
13. Indications (indicate code of ICD-10, if possible)	14. Single dose	15.Multiplicity of intake	16. Way of administration	17. Beginning of SMA therapy	18.End of SMA therapy
				/___/___/_____/	/___/___/_____/

III. INFORMATION ON RELATED MEDICINES (except used for correction the results of AR)

19. Concomitant MA (*trade name, druge form, manufacturer*)	20. Indications (indicate code of ICD-10, if possible)	21. Single dose	22. Multiplicity of intake	23. Way of administration	24. Beginning of therapy	25. End of therapy

26. Other important information (diagnosis, allergy, pregnancy with the indication of the term, etc.)

V. RESOURCES OFCORRECTION

□**Withdraw of SMA** Was the withdrawal of the SMA accompanied by the disappearance of the AR?□ **yes** □no
□ **Reassignment of the SMA** **Was there a renewal of the AR after the reappointment of the SMA?**□yes□no
□ **Change in the dosage regime of the SMA (decrease/ increase, indicate how much):** *Has the renewal of the AR/LO been marked after the change in the SMA dose regime?*□yes□no
□**Correction of AR/LO wasn't made**
□**Medicamental therapy AR/LO (**indicate MA, dose regimen, duration of the indication*):*

V. CAUSAL-INVESTIGATIONARY RELATIONS BETWEEN CLINICAL MANIFESTATIONS OF AR AND SMA

□certain	**□probable**	**□ possible**	**□uncertain**	**□not defined**	**□not classified**

VI. INFORMATION ABOUT THE COMMUNICATOR

27. FULL NAME OF CONTACT PERSON,tel/fax, email	**28.Notification was given by**	**29. Name and location of the institution or applicant**		
	□ physician □ pharmacist □ pharmaceutist □nurse □ paramedic □ obstetrician □ the applicant			
30. Sourse of notification (p. 30-32 only for communicator) □physician □patient □investigation □literature □other	**31. Notification number assigned by the applicant**	**32. Date of receiving by the applicant**	**33. Type of notification** □primary □current □final	**34. Date of completion**
The notification is filled in and provided at the GI "State Expert Center of the Ministry of Health of Ukraine", Department of Post-Registration Supervision, Ave. Ushinskogo, 40, Kiev, 03151; tel / fax: +38 044 4984358; **e-mail: vigilance@dec.gov.ua/; The electronic form of notification is available at http://www.dec.gov.ua/**				

IIa. ADDITIONAL INFORMATION IN THE EVENT OF SUCCESSIVE ADVERSE REACTION TO VACCINES OR TUBERCULOSIS ALLERGENS

<table>
<tr><td colspan="2">Category of immunization or tuberculin diagnostics</td><td colspan="3">Category of adverse event after immunization or tuberculin diagnostics</td></tr>
<tr><td colspan="2">□ large-scale campany
□ inoculation by age
□ at school
□ medical office for travelers
□ carrying out tuberculin diagnostics
□other</td><td colspan="3">□ response to a vaccine
□programme mistake
□ coincidence in time
□ reaction due to injection / fear of injection
□unknown</td></tr>
<tr><td colspan="2">Dose number (for vaccine)</td><td>Place of the vaccine introduction/ tuberculosis allergen</td><td colspan="2">Way of vaccine introduction/ tuberculosis allergen</td></tr>
<tr><td>□the first
□ the second
□the third</td><td>□ the fourth
□the fifth
□>the fifth</td><td rowspan="2">□left shoulder
□right shoulder
□shoulder (without specifying.)
□left hip
□right hip</td><td rowspan="2">□ hip (without specifying)
□lef tforearm
□righ forearm
□ forearm (without specifying)</td><td rowspan="2">□oraly
□intramascular
□ intracutaneously
□subcutaneously
□ other _____</td></tr>
<tr><td colspan="2">Best before /___/___/_____/</td></tr>
</table>

Kharkiv National Medical University

Department of Clinical Pharmacology and Internal Medicine
Research protocol of drugs efficiency and safety
(according to supervision)
Study and research work

Student_____
(Full name, year, group, department)
Supervisor_ _____

POTOCOL

of investigation of medical agent pharmacodinamic _____
Patient (Full name, age, body mass)_____
Clinical diagnosis: main disease_____
_____
_____
_____
Concominant disease_____
_____
_____
Date of investigation from c _____to_____

1. Patient's therapy (present in prescriptions of 5 the most important drugs including the drug which was chosen for detail analysis)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

2. Justification of the drug choice(international,trade names,chemical structure,particularities of drug introduction,pharmacokinetics, pharmacodinamics)

_____
_____
_____
_____
_____

3. Expected therapeutic effect _____
_____
_____
_____

4. Possible adverse effects_____ _____
_____
_____
_____

5. List the signs that will be used to monitor the therapeutic efficacy of drugs:

Before treatment	**After treatment**
Objective	
A)_____	_____
B)_____	_____
C)_____	_____
D)_____	_____
E)_____	_____
Physical	
A)_____	_____
B)_____	_____
C)_____	_____
D)_____	_____
E)_____	_____
Laboratory and instrumental	
A)_____	_____
B)_____	_____
C)_____	_____
D)_____	_____
E)_____	_____

6. List the symptoms that will control the side effects of drugs

Adverse effects	**Presents of reaction in patient (yes, no)**
Subjective	
A)_____	_____
Б)_____	_____
B)_____	_____
Г)_____	_____
Д)_____	_____
Physical	
A)_____	_____
B)_____	_____
C)_____	_____
D)_____	_____
E)_____	_____
Laboratory and instrumental	
A)_____	_____
B)_____	_____
C)_____	_____
D)_____	_____
E)_____	_____

7. Evaluation of combination therapy (consider co-administration of a drug that was evaluated with other drugs from Section 1: pharmacokinetic, pharmacodynamic, pharmaceutical compatibility)

_____
_____
_____
_____
_____

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

_____
_____
_____

Investigation was made by_____ Protocol was checked by_____

Clinical pharmacology

Self-study guide for 5 year English medium students

speciality “Dentisty”

Document compilers: L.R. Bobronnikova

I.I.Kniazkova

V.V. Zlatkina

V.D. Nemtsova

Yu.N.Shaposhnikova

A.S. Shalimova

I.A. Ilchenko

Responsible for the issue :V.D. Nemtsova