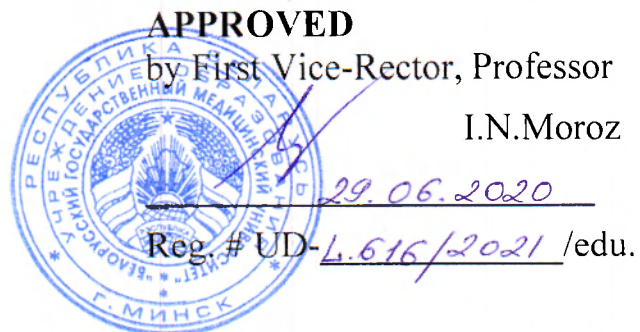


**MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
EDUCATIONAL INSTITUTION
BELARUSIAN STATE MEDICAL UNIVERSITY**

**Контрольный
экземпляр**



PHARMACOEPIDEMIOLOGY

**Curriculum of higher educational institution
in the educational discipline for the specialty:**

1-79 01 08 «Pharmacy»

The curriculum is based on the educational program «Pharmacoepidemiology», approved 10.11.2017, registration # УД-Л.616/1718/уч.

СОСТАВИТЕЛИ:

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I.N.Valchuk, PhD, Associate Professor of the Department of Epidemiology;

G.N.Chistenko, Head of the Department of Epidemiology, professor

RECOMMENDED FOR APPROVAL:

by the Department of Epidemiology of the Educational Institution «Belarusian State Medical University»
(protocol №22 of 10.06.2020)

by the Scientific Methodical Council of the Educational Institution «Belarusian State Medical University»
(protocol № 10 of 26.06.2020)

EXPLANATORY NOTE

«Pharmacoepidemiology» is an academic discipline that contains systematized scientific knowledge about the use and effects of drugs at the population level.

The aim of teaching and studying the academic discipline «Pharmacoepidemiology» is to form students and acquire scientific knowledge about the patterns and characteristics of the use and effects of drugs at the population level.

The tasks of studying pharmacoepidemiology are to acquire academic, social-personal and professional competencies by students, the basis of which is the ability to independently search for educational and information resources, master the methods of acquiring and understanding knowledge and skills, reflecting:

- general and specific issues of pharmacoepidemiology and evidence-based medicine;
- modern methods of studying drug consumption;
- pharmacoepidemiological studies using evidence-based medicine methods;
- assessment of the effects of using drugs at the population level.

The tasks of teaching the discipline are to form students' social, personal and professional competencies, the basis of which is knowledge and application of:

- methods of evidence-based medicine in pharmacoepidemiological studies;
- solving problems on the effectiveness and safety of medicines.

Teaching and successful study of the academic discipline «Pharmacoepidemiology» is carried out on the basis of the knowledge and skills acquired by students in the sections of the following disciplines:

Medical informatics. Application software, computer networks.

Fundamentals of Medical Statistics. Foundations of mathematical analysis. Statistical hypotheses and features of their testing. Processing and analysis of measurement results.

Pharmacology. General questions of pharmacology. Pharmacokinetics and pharmacodynamics of drugs.

Clinical pharmacology, pharmacological therapy. Evidence-based medicine. Types of pharmacological therapy. Side effects. Informational and advisory activities of a pharmacist in hospital, outpatient clinics and pharmacy organizations.

As a result of studying the discipline «Pharmacoepidemiology» the student should

know:

- the place of epidemiology and clinical epidemiology in the structure of biomedical disciplines;
- basic epidemiological concepts;
- terms and definitions of clinical epidemiology and evidence-based medicine;
- terms and definitions of pharmacoepidemiology;
- goals and objectives of pharmacoepidemiology;
- methods of epidemiological research in pharmacoepidemiology;
- frequency indicators used in pharmacoepidemiological studies;
- sources of evidence in structured databases;

- pharmacoepidemiology of the most important groups of drugs;
- pharmacoepidemiology of the most important infectious and non-infectious diseases;
- the purpose of pharmacovigilance.

be able to:

- use the knowledge of clinical epidemiology to solve professional problems;
- apply the ATC/DDD classification system, conduct ABC analysis and VEN analysis;
- to evaluate the design of epidemiological studies: descriptive-evaluative, randomized controlled trials, cohort studies, case-control studies;
- choose rational methods for studying the use of medicines at the population level;
- critically evaluate research results published in scientific (medical/pharmaceutical) journals;
- to determine the relationship between changes in the state of health of the population and the intake of medicines;
- to assess the risk/frequency of development of the identified effects of drug use in the population.

master:

- the most important concepts of pharmacoepidemiology;
- skills to search for evidence-based information in structured databases;
- methods of pharmacoepidemiology for the study of the pharmaceutical market;
- methods for determining the relationship between changes in the health status of the population and the intake of medicines;
- methods for assessing the risk/frequency of development of the identified effects of drug use in the population;
- methods of forming pharmacoepidemiological databases.

The structure of the curriculum for the academic discipline «Pharmacoepidemiology» includes 3 sections.

Total number of hours for the study of the discipline is 60 academic hours. Classroom hours according to the types of studies: lectures – 10 hours, practical classes – 30 hours, student independent work (self-study) – 20 hours.

Current assessment is carried out according to the syllabus of the specialty in the form of a credit (9 semester).

Form of higher education – full-time.

**ALLOCATION OF ACADEMIC TIME
ACCORDING TO SEMESTERS OF STUDY**

Code, name of the specialty	Semester	Number of academic hours					Form of current assessment
		total	in-class	including		out-of-class self-studies	
				lectures	laboratory studies (practical classes and seminars)		
1-79 01 08 «Pharmacy»	9	60	40	10	30	20	credit

THEMATIC PLAN

Section (topic) name	Number of hours of classroom work	
	lectures	practical classes
1. General and specific issues of pharmacoepidemiology and evidence-based medicine	10	-
1.1.Evidence-based medicine. Basic concepts	2	-
1.2.Pharmacoepidemiology. Basic concepts, goals and objectives	2	-
1.3.Pharmacoepidemiological aspects of the effectiveness and safety of drugs. Epidemiological rationale for pharmacovigilance	2	-
1.4.Pharmacoepidemiology of antimicrobial drugs	2	-
1.5.Pharmacoepidemiology of drugs used during pregnancy and lactation	2	-
2. Pharmacoepidemiology: study of drug consumption	-	9
2.1.Pharmacoepidemiological studies using the ATC/DDD system	-	3
2.2.Pharmacoepidemiological studies using ABC analysis	-	3
2.3.Pharmacoepidemiological studies using VEN-analysis	-	3
3. Pharmacoepidemiological studies using evidence-based medicine	-	21
3.1.Frequency indicators and their comparison in pharmacoepidemiological studies	-	3
3.2.Planning and conducting a population-based drug use study	-	3
3.3.Case-control studies	-	3
3.4.Cohort studies	-	3
3.5.Randomized controlled trials	-	3
3.6.Critical assessment of research results published in scientific (medical/pharmaceutical) journals. Evaluation criteria for scientific (medical/pharmaceutical) journals. Critical evaluation of a scientific publication (article)	-	6
Total hours	10	30

CONTENT OF THE EDUCATIONAL MATERIAL

1. General and specific issues of pharmacoepidemiology and evidence-based medicine

1.1. Evidence-based medicine. Basic concepts

The concept of evidence-based medicine, the preconditions for the use of the evidence system and the emergence of the corresponding terminology. The main approaches of doctors in decision-making and systems for determining the evidence of interventions. Algorithms for using evidence-based medicine. Epidemiology and clinical epidemiology in the structure of biomedical disciplines. Research types in clinical epidemiology and evidence-based medicine. The relevance of the development of evidence-based medicine and pharmacotherapy in modern society.

1.2. Pharmacoepidemiology. Basic concepts, goals and objectives

Pharmacoepidemiology is an integration discipline; definition of the concept; pharmacoepidemiology in the system of medical and biological disciplines; pharmacoepidemiology in the system of evidence-based medicine. Subject and method in pharmacoepidemiology. The purpose and objectives of pharmacoepidemiology. Types and stages of pharmaco-economic analysis. Assessment of the validity of the use of drugs, various methods of treatment and their safety for humans.

1.3. Pharmacoepidemiological aspects of the effectiveness and safety of drugs. Epidemiological rationale for pharmacovigilance

Medicines: application, history of the struggle for quality. Side effects of medicines. Classification of unwanted adverse drug reactions. Causes of side effects of drugs. The effectiveness and safety of the use of drugs. Monitoring of drug side effects. Methods for detecting undesirable side reactions of drugs. Study design for the study of the side effects of drugs at the population level. World Health Organization (WHO) Drug Monitoring Program. Pharmacovigilance. System of spontaneous messages. Notification of a suspected adverse drug reaction.

1.4. Pharmacoepidemiology of antimicrobial drugs

The concept of antibiotics, the history of their discovery and use in medicine. Mechanism and spectrum of action, the main groups of known antibiotics. Adverse reactions to taking antibiotics are their signs and causes. The value of antibiotics in the treatment of various infectious diseases. Clinical trials of drugs in biological media, animals and humans. Basic requirements for measuring instruments. Preparation and conduct of tests, assessment of their accuracy.

1.5. Pharmacoepidemiology of drugs used during pregnancy and lactation

Congenital fetal anomalies: relevance, distribution, association with medication during pregnancy. «Thalidomide» tragedy. Modern classifications of medicines according to the categories of their action on the fetus, based on the principles of evidence-based medicine. Drug treatment of cardiovascular diseases, pathology of the ENT (ear, nose, and throat) organs, diseases of the gastrointestinal tract in pregnant women. Features of the use of antimicrobial drugs in pregnant women. Relief of pain syndrome during pregnancy. Problems of providing pregnant and lactating women

with vitamins and microelements. Pharmacoeconomic analysis of drugs for the treatment of diseases during pregnancy. Features of the use of drugs during lactation.

2. Pharmacoepidemiology: study of drug consumption

2.1. Pharmacoepidemiological studies using the ATC/DDD system

Anatomical and therapeutic chemical classification (ATC) of drugs. International non-proprietary drug names. Drug codes in accordance with five-level characteristics: action on a specific anatomical organ or system, chemical, pharmacological, therapeutic properties. Specified Daily Dose of Medicines (DDD). Estimated (technical) nature of the established daily dose of drugs. DDD methodology is a universal system for measuring drug consumption. Calculation of indicators: the number of DDDs per 100 bed-days, the number of DDDs per 1000 population.

2.2. Pharmacoepidemiological studies using ABC analysis

Preconditions for the formation of ABC analysis. Pareto principle. ABC analysis technique. Ranking of medicines by resource intensity (financial costs). Grouping of medicines (groups A, B, C; 80%, 15%, 5%). ABC analysis of procurement of various medicines at the level of a healthcare organization, region, service or department, country. ABC analysis of drugs used for a specific pathology. The use of ABC analysis to assess the distribution of drugs by pharmacotherapeutic groups and to analyze the use of certain drugs within one pharmacotherapeutic group.

2.3. Pharmacoepidemiological studies using VEN-analysis

VEN analysis: definition of concept, purpose. An expert way of dividing drugs into groups (based on the principles of evidence-based medicine). The formal method of dividing drugs into groups (based on the assignment of indices depending on the inclusion of the drug in the national protocols for the treatment of the disease of interest: «V» - included, «N» - not included). Evaluation of VEN analysis results.

3. Pharmacoepidemiological studies using evidence-based medicine

3.1. Frequency indicators and their comparison in pharmacoepidemiological studies

Indicators of the ratio of two unrelated populations. Indicators of the share (specific weight) of the phenomenon in the structure of the entire population. Intensive indicators (frequency of the event in the aggregate). Incidence rates. Prevalence (morbidity) rates. Impact rate. Secondary disease rate. Person-time indicator (person-years). Mortality rates. Mortality rates.

3.2. Planning and conducting a population-based drug use study

Determination of the research goal. The need to read literature. The choice of the research method. Data collection (sampling data from medical documents, creating questionnaires, examining patients, creating pharmacoepidemiological databases). Preparation and training of personnel for data collection. Determination of the sample size and sampling. Inclusion/exclusion of patients in the sample. Response frequency. Data analysis.

3.3. Case-control studies

Purpose of the study. General research methodology. Inclusion of patients in the study. Inclusion and exclusion criteria. Research stages and scheme. Contingency

table (construction and calculation of indicators). Odds ratio. The merits and limitations of research.

3.4. Cohort studies

Purpose of the study. General research methodology. Types of cohort studies (prospective and retrospective). Principles of cohort formation and organization of cohort observation. Relative and absolute risks; additional risk and additional proportion of population risk. Advantages and disadvantages of cohort studies.

3.5. Randomized controlled trials

Purpose of the study. General research methodology. Inclusion of patients in the study. Inclusion and exclusion criteria. Research stages and scheme. Randomization. Types of randomized controlled trials (double, triple blind randomized trial). The merits and limitations of research.

3.6. Critical assessment of research results published in scientific (medical/pharmaceutical) journals. Evaluation criteria for scientific (medical/pharmaceutical) journals. Critical evaluation of a scientific publication (article)

Bibliometric indicators of the quality of a medical and pharmaceutical scientific journal. Impact factor. Citation Index. Hirsch index. Requirements for scientific medical and pharmaceutical publications. The main sections and the most important characteristics of the sections of a medical and pharmaceutical scientific publication (article), which provides research based on the principles of evidence-based medicine. Authorship, data analysis, conflict of interest. Good practice guidelines for scientific publishing.

EDUCATIONAL DISCIPLINE CURRICULAR CHART «PHARMACOEPIDEMIOLOGY»

Number of section, topic	Name of section, topic	Number of classwork hours		Independent work	Equipment	Form of knowledge assessment
		lectures	practical classes			
1.	General and specific questions of pharmacoepidemiology and evidence-based medicine	10	-	-	Multimedia projector	
1.1	Evidence-based medicine. Basic concepts	2	-	-		
1.2	Pharmacoepidemiology. Basic concepts, goals and objectives	2	-	-		
1.3	Pharmacoepidemiological aspects of the effectiveness and safety of drugs. Epidemiological rationale for pharmacovigilance	2	-	-		
1.4	Pharmacoepidemiology of antimicrobial drugs	2	-	-		
1.5	Pharmacoepidemiology of drugs used during pregnancy and lactation	2	-	-		
2.	Pharmacoepidemiology: study of drug consumption	-	9	6	Computer class	
2.1	Pharmacoepidemiological studies using the ATC/DDD system	-	3	2		Interview, report on classroom practical exercises with their oral defense
2.2	Pharmacoepidemiological studies using ABC analysis	-	3	2		Interview, report on classroom practical exercises with their oral defense

2.3	Pharmacoepidemiological studies using VEN-analysis	-	3	2	Interview, report on classroom practical exercises with oral defense, electronic tests
3.	Pharmacoepidemiological studies using evidence-based medicine	-	21	14	Computer lab with internet connection
3.1	Frequency indicators and their comparison in pharmacoepidemiological studies	-	3	2	Interview, quiz, report on classroom practical exercises with their oral defense
3.2	Planning and conducting a population-based drug use study	-	3	2	Interview, quiz, report on classroom practical exercises with their oral defense
3.3	Case-control studies	-	3	2	Interview, quiz, report on classroom practical exercises with their oral defense
3.4	Cohort studies	-	3	2	Interview, quiz, electronic test
3.5	Randomized controlled trials	-	3	2	Interview, quiz
3.6	Critical assessment of research results published in scientific (medical/pharmaceutical) journals. Evaluation criteria for scientific (medical/pharmaceutical) journals. Critical evaluation of a scientific publication (article)	-	6	4	Interview, electronic tests, credit
Total hours		10	30	20	

INFORMATION AND METHODOICAL PART

LITERATURE

Basic:

1. Pharmacoepidemiology, 3rd Edition [Электронный ресурс]. – 2018. – Режим доступа: <https://www.pdfdrive.com/pharmacoepidemiology-d20868879.html>. – Дата доступа 16.02.2020.
2. Clinical Epidemiology: The Essentials [Электронный ресурс]. – 2018. – Режим доступа: <https://www.pdfdrive.com/clinical-epidemiology-the-essentials-d158473834.html>. – Дата доступа 15.02.2020.

Additional:

1. Essentials of Pharmacoeconomics. [Электронный ресурс]. – 2018. – Режим доступа: <https://docplayer.net/89684649-Essentials-of-pharmacoeconomics.html>. – Дата доступа 15.02.2020.
2. Pharmacoepidemiology, Fifth Edition [Электронный ресурс]. – 2017. – Режим доступа: <https://pharmabookstore.com/blog/pharmacoepidemiology-fifth-edition/>. – Дата доступа 12.02.2020.
3. Basic epidemiology / R. Bonita, R. Beaglehole, T. Kjellström. 2nd edition [Электронный ресурс]. – 2017. – Режим доступа: [http://www.freebookcentre.net/medical_books_download/Basic-Epidemiology-\(PDF-226P\).html](http://www.freebookcentre.net/medical_books_download/Basic-Epidemiology-(PDF-226P).html). – Дата доступа 14.02.2020
4. Dictionary of Pharmacoepidemiology [Электронный ресурс]. – 2017. – Режим доступа: http://leg.ufpi.br/subsiteFiles/lapnex/arquivos/files/Dictionary_of_Pharmacoepidemiology.pdf. – Дата доступа 12.02.2020.
5. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology (Revision 7) [Электронный ресурс]. – 2011. – Режим доступа: http://www.encepp.eu/standards_and_guidances/documents/ENCePPGuideonMethStandardsinPE_Rev7.pdf. – Дата доступа 16.02.2020.
6. Pharmacoepidemiologic Studies: An Interrupted-Time Series Analysis On Drug Utilization And Evaluation Of Beneficial Or Adverse Drug Effects [Электронный ресурс]. – 2013. – Режим доступа: http://d-scholarship.pitt.edu/19269/1/Lo-Ciganic_ETD_August2013.pdf. – Дата доступа 14.02.2020.
7. Standards for causal inference methods in analyses of data from observational and experimental studies in patient-centered outcomes research [Электронный ресурс]. – 2012. – Режим доступа: <https://www.pdfdrive.com/division-of-pharmacoepidemiology-and-pharmacoeconomics-d9003273.html>. – Дата доступа 14.02.2020.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competences assessment:

1. Oral form:

- interview.

2. Writing form:

- abstracts;
- quiz.

3. Oral-written form:

- credit;
- reports on classroom practical exercises with their oral defense.

4. Technical form:

- electronic tests.

LIST OF PRACTICAL SKILLS

1. Evaluation of the design of epidemiological studies: descriptive and evaluative; randomized controlled; cohort; case-control studies.
2. Assessment of the development of adverse reactions when using drugs in the population.
3. Formation of pharmacoepidemiological databases.
4. Filling out a notification about a suspected adverse reaction to a medicinal product.

LIST OF LECTURES

1. Evidence-based medicine. Basic concepts.
2. Pharmacoepidemiology. Basic concepts, goals and objectives.
3. Pharmacoepidemiological aspects of the effectiveness and safety of drugs. Epidemiological rationale for pharmacovigilance.
4. Pharmacoepidemiology of antimicrobial drugs.
5. Pharmacoepidemiology of drugs used during pregnancy and lactation.

LIST OF PRACTICAL STUDIES

1. Pharmacoepidemiology: study of drug consumption: pharmacoepidemiological studies using the ATC/DDD system.
2. Pharmacoepidemiology: study of drug consumption: pharmacoepidemiological studies using ABC analysis.
3. Pharmacoepidemiology: study of drug consumption: pharmacoepidemiological studies using VEN analysis.
4. Pharmacoepidemiological studies using evidence-based medicine: frequency indicators and their comparison in pharmacoepidemiological studies.
5. Pharmacoepidemiological research using evidence-based medicine: planning and conducting a population-based drug use study.

6. Pharmacoepidemiological studies using evidence-based medicine: case-control studies.
7. Pharmacoepidemiological studies using evidence-based medicine: cohort studies.
8. Evidence-based pharmacoepidemiological studies: randomized controlled trials.
9. Critical assessment of research results published in scientific (medical/pharmaceutical) journals. Evaluation criteria for scientific (medical/pharmaceutical) journals.
10. Critical evaluation of a scientific publication (article).

PROTOCOL OF THE CURRICULUM APPROVAL BY OTHER DEPARTMENTS

Name of related disciplines	The department	Proposals for changes in the content of the curriculum of the institution of higher education in the academic discipline	Decision of the department, which designed the curriculum (date, protocol number)
Medical informatics	Medical and biological physics	There are no proposals for changes in the content of the curriculum	Coordinated, protocol № 22 dated 10.06.2020
Pharmacology	Pharmacology	There are no proposals for changes in the content of the curriculum	Coordinated, protocol № 22 dated 10.06.2020
Fundamentals of Medical Statistics	Public health and health	There are no proposals for changes in the content of the curriculum	Coordinated, protocol № 22 dated 10.06.2020

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Curriculum content, composition and the accompanying documents comply with the established requirements.

Dean of the Medical Faculty of International
Students of Educational Institution «Belarusian
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26. 06. 2020

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Methodologist of Educational Institution
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