

Al-Farabi Kazakh National University  
Faculty Medicine and Health Care  
Education program on specialty:  
«Public Health »

**GUIDELINE TO CLASSES OF COURSE “EPIDEMIOLOGY”**

3 credits

Author:

FA. Iskakova, MD, PhD

Almaty, 2019

CLASSES TOPICS

OF COURSE "EPIDEMIOLOGY"

Content	Topic	N of hours	Max. scores
<b>Module I. Bases and concepts of Epidemiology</b>			
Class 1	Definition, purpose and objectives of Epidemiology. Causal thinking. Core epidemiologic Functions. The Epidemiologic Approach.	2	14
Class 2	Concepts of Disease Occurrence. Natural History and Spectrum of Disease. Chain of Infection. Epidemic Disease Occurrence.	2	14
Class 3	Measures of risk. Frequency Measures. Morbidity and Mortality Frequency Measures. Natality (Birth) Measures. Measures of Association. Measures of Public Health Impact. Quantitative and Qualified Epidemiology.	2	14
	MIWT. Consultation for masters independent work carry out on topics 1-3		
	MIW 1. Essay and overview of articles on 1-3 class topics.		30
Class 4	Epidemiological Investigation. Investigating an Outbreak.	2	14
Class 5	Public Health Surveillance. Purpose and Characteristics of Public Health Surveillance. Identifying Health Problems for Surveillance. Identifying or Collecting Data for Surveillance. Analyzing and Interpreting Data . Disseminating Data and Interpretations. Evaluating and Improving Surveillance.	2	14
	MT 1		100
<b>Module II. Methodological approaches in Epidemiology</b>			
Class 6	Design of Epidemiological Studies. Descriptive studies. Descriptive studies: case reports, case series, ecological and cross-sectional.: strength and limitations.		
Class 7	Analytical studies. Case-control study: strength and limitations, measure association, using in Medicine. Measures of association or measures of excess risk. OR, RR, AR, AR%, PAR, PAR%.. Practical work: analysis of case- control study using scientific articles from websites as an example.	2	14
Class 8	Analytical studies. Cohort study: strength and limitations, measure association, measurement of expose in studies (RR, AR, AR%, PAR,PAR%). Using cohort studies in Medicine. Practical work: analysis of case- control study using scientific articles from websites as an example.	2	14
	MIWT 2. Consultation for masters' independent work carry out on topics 6-7. Text and graphic content, preparation Power Point Presentation.		
	MIW 2. Analytical studies in Medicine.		15
Class9	Experimental studies Experimental studies. Randomized controlled trial and non-randomized trial. Stratified, crossover, factorial design and group randomization.		14

	Strength and limitations. Practical work using scientific articles from websites as an example.		
Class 10	Bias and confounding factors in studies Overview of epidemiological studies. Practical work using scientific articles from websites as an example.	2	14
	Midterm exam.		100
Module III. Types of Epidemiology			
Class 11	Diagnostic and screening tests. Sensitivity and specificity of tests.	2	14
Class 12	Statistical methods in Epidemiology. Meta-Analysis. Practical work using scientific articles from websites as an example.	2	14
	MIWT 4. Consultation of masters' independent work carry out on topics 11-12.		
	MIW 4. Clinical Trial 1.		15
Class 13	DEPTH model in Medicine. Implementation of epidemiologic studies in Medicine. Practical work using scientific articles from websites as an example.	2	14
Class 14	Exposure-Oriented Epidemiology: Occupational, Environmental, Nutritional, Radiation, Physical Activity Epidemiology .	2	14
Class	MIWT 5. Consultation of masters' independent work carry out on topics 13-14.		
Class	MIW 5. Clinical Epidemiology and Evidence-Based Medicine.		15
Class 15	Outcome-Oriented Epidemiology: Infectious Disease Epidemiology, Cardiovascular Disease and Health, Cancer Epidemiology, Epidemiology of Diabetes, Epidemiology of Psychiatric Disorders.	2	14
	MT 3		100
	Final Exam		100

### Module I. Bases and concepts of Epidemiology

Class 1. Introduction to Epidemiology. Definition of Epidemiology. History of Epidemiological methods and concepts. Core Epidemiologic Functions. Causal thinking. Core The Epidemiologic Approach.

Content. Epidemiology is the study of frequency and determinants related with diseases that are distributed in specific group of population. In recent years epidemiology has become an increasingly important approach in both public health and clinical practice. Epidemiology is the basic science of disease prevention and plays major roles in the development and evaluation of public policy as well as in social and legal arenas.

Epidemiology studies using of epidemiologic studies in Medicine. So Epidemiology and Clinical Epidemiology have close relationship for solving problem of People's health. Quantitative and Qualified Epidemiology.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know classification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.

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Class. 2. Concepts of Disease Occurrence. Natural History and Spectrum of Disease. Chain of Infection. Epidemic Disease Occurrence.

Content. A critical premise of epidemiology is that disease and other health events do not occur randomly in a population. A number of models of disease causation have been proposed. The traditional model for infectious disease consists of an external agent, a susceptible host, and an environment that brings the host and agent together. In this model, disease results from the interaction between the agent and the susceptible host in an environment that supports transmission of the agent from a source to that host.

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Class 3. Quantitative and Qualified Epidemiology. Measures of risk. Frequency Measures. Morbidity and Mortality Frequency Measures. Natality (Birth) Measures. Measures of Association. Measures of Public Health Impact.

Content. Quantitative and qualitative research use different research methods to collect and analyze data, and they allow you to answer different kinds of research questions. For quantitative data it used statistical analysis methods to test, relationships between variables; and for qualitative data it used methods such as thematic analysis to interpret patterns and meanings in the data. Qualitative vs. quantitative research. A descriptive research design use a wide variety of quantitative and qualitative methods to investigate one or more variables. The researcher observes and measures variables related with disease and outcomes of them.

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Class 4. Epidemiological Investigation. Investigating an Outbreak.

Content. Outbreaks of disease is the occurrence of more cases than expected or occur frequently. Each day, health departments learn about cases or outbreaks that require investigation. One way is to analyze surveillance data is reports of cases of communicable diseases that are routinely sent by laboratories and healthcare providers to health departments. Investigation indicated that the increase in gastroenteritis was probably attributable to the consumption of meat that had spoiled during the power failure. Steps of outbreak investigations are Prepare for field work, Establish the existence of an outbreak, Verify the diagnosis, Construct a working case definition, Find cases systematically and record information, Perform descriptive epidemiology, Develop hypotheses, Evaluate hypotheses epidemiologically, As necessary, reconsider, refine, and re-evaluate hypotheses, Compare and reconcile with laboratory and/or environmental studies, Implement control and prevention measures, Initiate or maintain surveillance, Communicate findings.

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Class 5. Public Health Surveillance.

Content. The health department is responsible for protecting the public's health using program named Public Health Surveillance which have function of survey and control over population health. Objectives of PHS are Identifying Health Problems for Surveillance, and Collecting Data for Surveillance, Analyzing and Interpreting Data, Disseminating Data and Interpretations, Evaluating and Improving Surveillance, Summary, References.

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Module II. Methodological approaches in Epidemiology

Class 6. Concepts and Design of Epidemiological Studies. Descriptive studies: case reports, case series, ecological and cross-sectional.

Content. Epidemiologic studies: observational and experimental. Descriptive studies identify patterns among cases and in populations by time, place and person. Descriptive research answers what, when, where, when and how questions, but not why and how questions. Hypothesis is formed on the basis of a descriptive study. Case-report, case-series, ecological and cross-sectional studies. Estimation of advantages and disadvantages. Using in Medicine. Measurement of associations. An ecological study design is used to monitor population health, make large-scale comparisons, to study the relationship between population-level exposure to risk factors and disease. In a cross-sectional study, the investigator measures the outcome and the exposures in the study participants at the same time on the inclusion and exclusion criteria set for the study.

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Class 7. Analytical studies. Case-control study: strength and limitations, using in Medicine. Measures of association or measures of excess risk. OR, RR, AR, AR%, PAR, PAR%.

Content. Analytic studies are then undertaken to test specific hypotheses. Samples of subjects are identified and information about exposure status and outcome is collected. The essence of an analytic study is that groups of subjects are compared in order to estimate the magnitude of association between exposures and outcomes. A case-control study is designed to help determine if an exposure is associated with an outcome (i.e., disease or condition of interest). The case-control study can be described simply. First, identify the cases (a group known to have the outcome) and the controls (a group known to be free of the outcome). In the analysis stage, calculate the frequency of each of the measured variables in each of the two groups. As a measure of the strength of the association between an exposure and the outcome, case-control studies yield the odds ratio. An odds ratio is the ratio of

the odds of an exposure in the case group to the odds of an exposure in the control group.

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Class 8. Analytical studies. Cohort study: strength and limitations, measure association, using in Medicine. Practical work: analysis of case- control study using scientific articles from websites as an example. Evaluation and measurement of the occurrence of diseases. Measurement of exposure in studies: RR, OR, AR, AR%, PAR, PAR%. Practical work using scientific articles from websites as an example.

Content. Cohort study is the main analytical study that focuses on exposition of risk factors. They were open and closed, retrospective and prospective. Evaluation and measurement of the occurrence of diseases. Measurement of exposure in studies using RR, OR, AR, AR%, PAR, PAR%. Practical work using scientific articles from websites as an example. Summary measures of population health are measures that combine information on mortality and non-fatal health outcomes to represent the health of a particular population as a single number. A wide array of summary measures have been proposed (for example, active life expectancy, disability-free life expectancy, dementia-free life expectancy, disability-adjusted life expectancy, health-adjusted life expectancy, healthy life-years, Years of Healthy Life, disability-adjusted life years, etc.). On the basis of a simple survivorship curve, these measures can be divided broadly into two families: health expectancies and health gaps.

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Class 9. Experimental studies. Randomized controlled trial and non-randomized trial. Stratified, crossover, factorial design and group randomization. Design of clinical trials (phases, safety and effectiveness of drugs).

Content. Experimental studies are studies in which the investigator artificially manipulates study factors or subjects, such as therapeutic regimen, or some other parameter. An experimental study is the preferred means of hypothesis testing in most laboratory settings, and relevant methods are subject to continuing improvements. Types of experimental studies are randomized and non-randomized trials. Randomized controlled trial: (RCT) A study in which people are allocated at random (by chance alone) to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be a standard practice, a placebo ("sugar pill"), or no intervention at all. Someone who takes part in a randomized controlled trial (RCT) is called a participant or subject. RCTs seek to measure and compare the outcomes after the participants receive the interventions. Because the outcomes are measured, RCTs are quantitative studies.

In sum, RCTs are quantitative, comparative, controlled experiments in which investigators study two or more interventions in a series of individuals who receive them in random order. The RCT is one of the simplest and most powerful tools in clinical research.

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Class 10. Bias and confounding factors in studies. Overview of epidemiological studies. Practical work using scientific articles from websites as an example.

Content. Bias may be defined as any systematic error in an epidemiological study that results in an incorrect estimate of the true effect of an exposure on the outcome of interest. Bias results from systematic errors in the research methodology. More than 50 types of bias have been identified in epidemiological studies, but for simplicity they can be broadly grouped into two categories: information bias and selection bias. Confounding provides an alternative explanation for an association between an exposure (X) and an outcome. It occurs when an observed association is in fact distorted because the exposure is also correlated with another risk factor (Y). This risk factor Y is also associated with the outcome, but independently of the exposure under investigation, X. As a consequence, the estimated association is not that same as the true effect of exposure X on the outcome.

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### Module III. Module III. Types of Epidemiology

Class 11. Diagnostic and screening tests. Sensitivity and specificity of tests.

Content. A diagnostic test is used to determine the presence or absence of a disease when a subject shows signs or symptoms of the disease. A screening test identifies asymptomatic individuals who may have the disease. The diagnostic test is performed after a positive screening test to establish a definitive diagnosis.

The probability of having the disease, given the results of a test, is called the predictive value of the test. Positive predictive value is the probability that a patient with a positive (abnormal) test result actually has the disease. Negative predictive value is the probability that a person with a negative (normal) test result is truly free of disease.

Sensitivity is the ability of the test to identify correctly those who have the disease. Specificity is the ability of the test to identify correctly those who do not have the disease.

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Class 12. Statistical methods in Epidemiology. Meta-Analysis. Practical work using scientific articles from websites as an example.

Content. Statistical methods and techniques used in Epidemiology. Epidemiologic studies are determined by the study design and data type. Principles of Data Analysis, Statistical Thinking, Multivariate Analysis, Handling of Data Problems, Meta-Analysis. Meta-analysis is a quantitative, formal, epidemiological study design used to systematically assess the results of previous research to derive conclusions about that body of research. Meta-analysis combines information from multiple scientific publications and can increase the chances of finding true positives among the identified associations. Meta-analysis is an analytical tool that permits the evaluation of a diagnostic or therapeutic modality through the appropriate use of previously published smaller studies.

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Class 13. DEPTH model in Medicine. Implementation of epidemiologic studies in Medicine. Practical work using scientific articles from websites as an example.

Content. DEPTH model in Medicine. There are diagnostic, etiologic, prognostic and therapeutic researches for solving problem of Clinical Medicine.

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Class 14. Exposure-Oriented Epidemiology: Occupational, Environmental, Nutritional, Radiation, Physical Activity Epidemiology.

Content. Epidemiology has been defined as the study of the effects of workplace exposures on the frequency and distribution of diseases and injuries in the population. Thus it is an exposure-oriented discipline versus of outcome –oriented Epidemiology as Epidemiology of Infectious diseases, cardiovascular diseases etc. Types of Exposure-Oriented Epidemiology are Occupational, Environmental, Nutritional, Radiation, Physical Activity Epidemiology.

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Class 15. Outcome-Oriented Epidemiology: Infectious Disease Epidemiology, Cardiovascular Disease and Health, Cancer Epidemiology, Epidemiology of Diabetes, Epidemiology of Psychiatric Disorders.

Content. Outcome-Oriented Epidemiology as Infectious Disease Epidemiology, Cardiovascular Disease and Health, Cancer Epidemiology, Epidemiology of Diabetes, Epidemiology of Psychiatric Disorders based on results of outcomes related with exposure determinants (reasons and risk factors). They are the major cause of burden: morbidity, mortality and disorders.

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6. Principles and methods of Epidemiology. 3-d Edition. R. Dicker Ooffice of epidemiologic program CДC, USAID. -2012.-457 P.
7. Principles of Epidemiology in Public Health Practice. Third Edition. An introduction to Epidemiology and Biostatics.US, CDC, Atlanta. -2012.-6-75 p.
8. Hennekens, C., & Buring, J. (1987). Epidemiology in Medicine, Boston/Toronto: Little, Brown and Company.
9. Kelsey, J., Whittemore, A., Evans, A. & Thompson, D. (1996). Methods in Observational Epidemiology, Second Edition, New York: Oxford University Press.

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3. [www.medline](http://www.medline)
4. [www.cockraine.library](http://www.cockraine.library)
5. [www.PubMed](http://www.PubMed)

Class 3. Descriptive studies: ecological and cross-sectional studies. Estimation of advantages and disadvantages. Using in Medicine. Measurement of associations.

Content. An ecological study design is used to monitor population health, make large-scale comparisons, to study the relationship between population-level exposure to risk factors and disease, or in order to look at the contextual effect of risk factors on the population. In a cross-sectional study, the investigator measures the outcome and the exposures in the study participants at the same time on the inclusion and exclusion criteria set for the study. The investigator follow: the study to assess the exposure and the outcomes.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions.

Purpose of class: to form knowledge, practical skills and professional competencies in provide ecological and cross-sectional study, analysis and making decisions.

Methodical recommendations: students should know how to organize ecological and cross-sectional studies, measure of prevalence of diseases and analyze results.

Required Reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

Recommended Reading:

2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
4. Webb P and Bain C. Essential Epidemiology: An introduction for Students and Health Professionals. Second Edition. Cambridge University Press. 2011.
5. Wolfgang, A. Handbook of Epidemiology. Vol.1//Ahrens Wolfgang, Peugeot Iris. - 2 ed.- Springer Reference, 2014.- 469 p.
6. Principles and methods of Epidemiology. 3-d Edition. R. Dicker Ooffice of epidemiologic program CДC, USAID. -2012.-457 P.
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Class 4. Design and Planning of an epidemiological study: problem definition, scientific justification, protocol, design, measurement of associations of exposure to risk factors and disease outcomes, the effect of confounding factors and conclusion.

Content. There are basic principles and practical issues in designing and planning epidemiological studies. good epidemiological study relies basically on planning, and planning and planning again. And planning refers to thinking ahead, to ensure that the study is probability capable of answering to the research question and predicting all things that can happen to bias the study – we must consider all issues from conceptual framework in which the study is based on, objectives, data collection and analysis and how those elements contribute to achieve the objectives of the study. The place to start doing this is the research protocol.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know types of descriptive studies, choose appropriate for a research clinical questions.

Required Reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

Recommended Reading:

2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
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Class 5. Overview of observational descriptive studies. Estimation of advantages and disadvantages. Choosing and using in Clinical Practice.

Content. Descriptive study is one that is designed to describe the distribution of one or more variables, without regard to any causal or other hypothesis. Descriptive studies can be of several types, namely, case reports, case series, cross-sectional studies, and ecological studies. In the first



three of these, data are collected on individuals, whereas the last one uses aggregated data for groups.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know

Required Reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

Recommended Reading:

2. Rothman K., Modern Epidemiology, 3rd Edition, 2008

3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007

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## Module II Analytical studies

Class 6. Analytical studies. Case-control study: strength and limitations, measure association, using in Medicine. Practical work: analysis of case- control study using scientific articles from websites as an example.

Content. Analytic studies are then undertaken to test specific hypotheses. Samples of subjects are identified and information about exposure status and outcome is collected. The essence of an analytic study is that groups of subjects are compared in order to estimate the magnitude of association between exposures and outcomes. Case-control study.

Tasks: define and explain the distinguishing features of a case-control study; identify the study design when reading an article or abstract.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know, can organize and provide case-control study, measure OR, analyze significance on P value.

Required Reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

Recommended Reading:

2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
4. Webb P and Bain C. Essential Epidemiology: An introduction for Students and Health Professionals. Second Edition. Cambridge University Press. 2011.
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Class 7. Analytical studies. Cohort study: strength and limitations, measure association, using in Medicine. Practical work: analysis of case- control study using scientific articles from websites as an example.

Content. Analytic studies are then undertaken to test specific hypotheses. Samples of subjects are identified and information about exposure status and outcome is collected. The essence of an analytic study is that groups of subjects are compared in order to estimate the magnitude of association between exposures and outcomes. Cohort study.

Tasks: Describe the difference between descriptive and scientific/analytic epidemiologic studies in terms of information/evidence provided for medicine and public health; define and explain the distinguishing features of a cohort study; describe and identify the types of epidemiologic questions that can be addressed by cohort studies; define and distinguish among prospective and retrospective cohort studies using the investigator as the point of reference; define and explain the distinguishing features of a case-control study; explain the distinguishing features of an intervention study; identify the study design when reading an article or abstract.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know, can organize and provide cohort study, measure RR, analyze significance on P value.

Required Reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

Recommended Reading:

2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
4. Webb P and Bain C. Essential Epidemiology: An introduction for Students and Health Professionals. Second Edition. Cambridge University Press. 2011.
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Class 8. Evaluation and measurement of the occurrence of diseases. Measurement of expose in studies: RR, OR, AR, AR%, PAR, PAR%. Practical work using scientific articles from websites as an example.

Content. Summary measures of population health are measures that combine information on mortality and non-fatal health outcomes to represent the health of a particular population as a single number. A wide array of summary measures have been proposed (for example, active life expectancy, disability-free life expectancy, dementia-free life expectancy, disabilityadjusted life expectancy, health-adjusted life expectancy, healthy life-years, Years of Healthy Life, disability-adjusted life years, etc.). On the basis of a simple survivorship curve, these measures can be divided broadly into two families: health expectancies and health gaps.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know how evaluate and measure the occurrence of diseases.

Required Reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013
2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
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Class 9. Exposure or outcome. Measurement of exposure in studies: RR, OR, AR. Practical work using scientific articles from websites as an example.

Content. The term “exposure” can be applied to the primary explanatory variable of interest and to other variables that may be associated with the outcome, such as confounders or effect modifiers, which also must be addressed in the analysis of the primary outcome.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know how estimate exposure and outcome of epidemiologic studies.

Required reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013
2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
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Class 10. Bias and confounding factors in studies. Practical work using scientific articles from websites as an example.

Content. Bias may be defined as any systematic error in an epidemiological study that results in an incorrect estimate of the true effect of an exposure on the outcome of interest. Bias results from systematic errors in the research methodology. More than 50 types of bias have been identified in epidemiological studies, but for simplicity they can be broadly grouped into two categories: information bias and selection bias. Confounding provides an alternative explanation for an

association between an exposure (X) and an outcome. It occurs when an observed association is in fact distorted because the exposure is also correlated with another risk factor (Y). This risk factor Y is also associated with the outcome, but independently of the exposure under investigation, X. As a consequence, the estimated association is not that same as the true effect of exposure X on the outcome.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know bias and confounding, and can estimate them in epidemiologic studies.

Required Reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

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### Module III. Experimental studies

Class 11. Experimental studies. Randomized controlled trial and non-randomized trial. Stratified, crossover, factorial design and group randomization. Strength and limitations. Practical work using scientific articles from websites as an example.

Content. Experimental studies are studies in which the investigator artificially manipulates study factors or subjects, such as therapeutic regimen, or some other parameter. An experimental study is the preferred means of hypothesis testing in most laboratory settings, and relevant methods are subject to continuing improvements. Types of experimental studies are randomized and non-randomized trials.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know types and criteria of experimental studies, analyze the scientific articles and can take part in them.

Required Reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013
2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
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Class 12. Design of clinical trials (phases, safety and effectiveness of drugs). Algorithm of clinical trial.

Content. Clinical trials for drug development are classically divided into four phases: I to IV. After preclinical study in the laboratory, a drug is generally first tested in humans in Phase I trials that generate key safety and pharmacokinetic and pharmacodynamic data for small numbers of participants. Phase I trials are generally dose-finding trials that might aim to establish the maximally tolerated dose for adults or identify the dosing for children that yields exposure equivalent to that of adults. Phase II trials confirm safety and explore efficacy to facilitate decisions about further development. Phase III trials are pivotal trials that confirm safety and establish efficacy among a larger number of participants; Phase III data are generally required for regulatory approval of a new drug for adults. Phase IV trials generate data on long-term safety and/or efficacy for a new drug after it has been licensed in real-world conditions across different populations.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know phases of clinical trials and analyze scientific articles, and can take part in trials.

Required reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013
2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
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Class 13. Diagnostic and screening tests. Sensitivity and specificity of tests.

Content. A diagnostic test is used to determine the presence or absence of a disease when a subject shows signs or symptoms of the disease. A screening test identifies asymptomatic individuals who may have the disease. The diagnostic test is performed after a positive screening test to establish a definitive diagnosis.

The probability of having the disease, given the results of a test, is called the predictive value of the test. Positive predictive value is the probability that a patient with a positive (abnormal) test result actually has the disease. Negative predictive value is the probability that a person with a negative (normal) test result is truly free of disease.

Sensitivity is the ability of the test to identify correctly those who have the disease. Specificity is the ability of the test to identify correctly those who do not have the disease.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know using diagnostic and screening tests and how estimate sensitivity and specificity of them for recommendation to Clinical Medicine.

Required Reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013
2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
3. Pickles A. Epidemiological Methods in Life Course Research, 1st Edition, 2007
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Class 14. DEPTH model in Medicine. Implementation of epidemiologic studies in Medicine. Practical work using scientific articles from websites as an example.

Content. DEPTH model in Medicine. There are diagnostic, etiologic, prognostic and therapeutic researches for solving problem of Clinical Medicine.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know using epidemiologic methods in Medicine.

Required Reading:

1. Aschengrau A., *Essentials of Epidemiology in Public Health*, 3rd Edition, 2008

**Recommended reading:**

1. Gordis: *Epidemiology*, 5th Edition, Saunders 2013
2. Rothman K., *Modern Epidemiology*, 3rd Edition, 2008
3. Pickles A. *Epidemiological Methods in Life Course Research*, 1st Edition, 2007
4. Webb P and Bain C. *Essential Epidemiology: An introduction for Students and Health Professionals*. Second Edition. Cambridge University Press. 2011.
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Class 15. Overview of Clinical Trials. Discussion.

Content. Clinical trials are conducted to collect data regarding the safety and efficacy of new drug and device development. There are several steps and stages of approval in the clinical trials process before a drug or device can be sold in the consumer market, if ever. Drug and device testing begins with extensive laboratory research which can involve years of experiments in animals and human



cells. If the initial laboratory research is successful, researchers send the data to the Food and Drug Administration (FDA) for approval to continue research and testing in humans. Once approved, human testing of experimental drugs and devices can begin and is typically conducted in four phases. Each phase is considered a separate trial and, after completion of a phase, investigators are required to submit their data for approval from the FDA before continuing to the next phase.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make decisions.

Purpose of class: to form knowledge, practical skills and professional competencies in

Methodical recommendations: students should know types of clinical trial, design and planning; organize and provide them, analyze endpoints, and make conclusion.

Required reading:

1. Aschengrau A., Essentials of Epidemiology in Public Health, 3rd Edition, 2008

Recommended reading:

1. Gordis: Epidemiology, 5th Edition, Saunders 2013

2. Rothman K., Modern Epidemiology, 3rd Edition, 2008

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