

Al-Farabi Kazakh National University
Faculty Medicine and Health Care
Education program on specialty:
«8D101 Medicine»

**GUIDELINE TO CLASSES OF COURSE “MODERN EPIDEMIOLOGIC
METHODS IN MEDICINE”**

3 credits

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CLASSES TOPICS

OF COURSE "MODERN EPIDEMIOLOGIC METHODS IN MEDICINE"

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Class 1	Definitions and relationship of Epidemiology and Clinical Epidemiology. Quantitative and Qualified Epidemiology.	
Class 2	Classification of Epidemiologic studies, using of systematization criteria. Observational research. General information of descriptive methods, general information: case study, case reports, case series.	
Class 3	Descriptive studies: ecological and cross-sectional studies. Estimation of advantages and disadvantages. Using in Medicine. Measurement of associations.	
Class 4	Planning and design 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.	
Class 5	Overview of observational descriptive studies. Estimation of advantages and disadvantages. Choosing and using in Clinical Practice.	
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.	
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.	
Class 8	Evaluation and measurement of the occurrence of diseases. Measurement of expose in studies: RR, OR, AR. Practical work using scientific articles from websites as an example.	
Class 9	Exposure or outcome. Measurement of expose in studies: RR, OR, AR. Practical work using scientific articles from websites as an example.	
Class 10	Bias and confounding factors in studies. Practical work using scientific articles from websites as an example.	
Module III. Experimental studies		
Class 11	Experimental studies 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.	
Class 12	Design of clinical trials (phases, safety and effectiveness of drugs). Algorithm of clinical trial.	
Class 13	Diagnostic and screening tests. Sensitivity and specificity of tests.	
Class 14	DEPTH model in Medicine. Implementation of epidemiologic studies in Medicine. Practical work using scientific articles from websites as an example.	
Class 15	Overview of Clinical Trials. Discussion.	

Module I. Introduction to modern epidemiologic studies.

Class 1. Definitions and relationship of Epidemiology and Clinical Epidemiology. Quantitative and Qualified Epidemiology.

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. Clinical 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 understanding of purposes of Epidemiology and using of epidemiologic methods of research in Medicine.

Methodical recommendations: students should know definition, purposes, main tools and using of epidemiologic approach and methods for solving problems related with Health in Population.

Required Reading:

Class 2. Classification of Epidemiologic studies, using of systematization criteria. Observational research. General information of descriptive methods, general information: case study, case reports, case series.

Content. Epidemiologic studies divide to observational and interventional. Observational studies can be descriptive and analytical. Descriptive studies identify patterns among cases and in populations by time, place and person. From these observations, epidemiologists develop hypotheses about the causes of these patterns and about the factors that increase risk of disease. Descriptive research answer what, when, where, when and how questions, but not why and how questions. Hypothesis is formed on base of descriptive study. 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. In other words, epidemiologists can use descriptive epidemiology to generate hypotheses.

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.

Required Reading:

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.
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.
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.

Electronic source:

1. www.who.org
2. www.cdc.gov
3. www.medline
4. www.cockraine.library
5. 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 follows 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.
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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
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.
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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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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

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 Office of epidemiologic program C/D/C, USAID. -2012.-457 P.

7. Principles of Epidemiology in Public Health Practice. Third Edition. An introduction to Epidemiology and Biostatistics.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

4. www.cochrane.library

5. www.PubMed

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; 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.
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.
7. Principles of Epidemiology in Public Health Practice. Third Edition. An introduction to Epidemiology and Biostatistics.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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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.
5. Wolfgang, A. Handbook of Epidemiology. Vol.1//Ahrens Wolfgang, Peugeot Iris. - 2 ed.- Springer Reference, 2014.- 469 p.

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7. Principles of Epidemiology in Public Health Practice. Third Edition. An introduction to Epidemiology and Biostatistics.US, CDC, Atlanta. -2012.-6-75 p.
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5. www.PubMed

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
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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5. www.PubMed

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 to 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
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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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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5. www.PubMed

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

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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6. Principles and methods of Epidemiology. 3-d Edition. R. Dicker Office of epidemiologic program C/C, USAID. -2012.-457 P.

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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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1. www.who.org

2. www.cdc.gov

3. www.medline

4. www.cockraine.library

5. www.PubMed

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
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 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 decisions.

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:

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2. Rothman K., Modern Epidemiology, 3rd Edition, 2008
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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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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.
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 Office of epidemiologic program C/D/C, USAID. -2012.-457 P.
7. *Principles of Epidemiology in Public Health Practice*. Third Edition. An introduction to Epidemiology and Biostatistics. 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.

Electronic source:

1. www.who.org
2. www.cdc.gov
3. www.medline
4. www.cockraine.library
5. www.PubMed

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

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.

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7. Principles of Epidemiology in Public Health Practice. Third Edition. An introduction to Epidemiology and Biostatistics. US, CDC, Atlanta. -2012.-6-75 p.

8. Hennekens, C., & Buring, J. (1987). Epidemiology in Medicine, Boston/Toronto: Little, Brown and Company.

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