КАЗАХСКИЙ НАЦИОНАЛЬНЫЙ УНИВЕРСИТЕТ ИМ.АЛЬ-ФАРАБИ
КАФЕДРЫ ЭПИДЕМИОЛОГИИ, БИОСТАТИСТИКИ И ДОКАЗАТЕЛЬНОЙ МЕДИЦИНЫ

РУКОВОДСТВО КУРСА

«ЭТИКА И МЕТОДОЛОГИЯ НАУЧНЫХ ИССЛЕДОВАНИЙ»

5 кредитов

СОСТАВИТЕЛЬ: ИСКАКОВА Ф.А., и.о.доцента, д.м.н. КР, к.м.н.РК

Almaty, 2021

Темы семинарских занятий дисциплины «Этика и методология научных исследований»

№	Темы занятий	Количество часов	Максимальный балл
Модуль 1. Методологические основы научного знания			
1	Семинар I. Определение науки и научного исследования. Этапы научного исследования.	2	12
2	Семинар 2. Методология и классификация научных исследований.	2	12
3	Семинар 3. Стандарты и требования к проведению научного исследования в области здравоохранения.	2	12
4	Семинар 4. Теоретические исследования: методы, особенности, структура и модели.	2	12
5	Семинар 5. Планирование и методы экспериментального исследования. Методы измерения результатов исследования. Организация рабочего места экспериментатора. Влияние разных факторов на качество эксперимента.	2	12
	Рубежный контроль		100
Модуль 2. Этапы научного исследования			
6	Семинар 6. Выбор темы, методика планирования научно-исследовательской работы. Источники информации.	2	12
7	Семинар 7. Обработка результатов научного исследования.	2	12
8	Семинар 8. Графические методы анализа данных.	2	12
9	Семинар 9. Научные результаты и их оформление. Схема создания научной публикации. Работа над публикацией. Поиск и составление списка использованных литературных источников.	2	12
10	Семинар 10. Социальные функции наука. Противоречия в науке и практике.	2	12
	МидтермРу		100
Модуль 3. Основы этики в научных исследованиях.			
11	Семинар 11. Этические и правовые основы научных исследований.	2	12
12	Семинар 12. Международные документы по регулированию научных исследований. Этические комитеты: статус, функции и задачи.	2	12
13	Семинар 13. Доклинические исследования. Этические нормы использования животных в научных исследованиях.	2	12
14	Семинар 14. Клинические исследования. Этические нормы и принципы в клинических исследованиях.	2	12
15	Семинар 15. Этические и правовые аспекты в	2	12

	специальных вопросах исследований (дети, беременные женщины и больные с психическими расстройствами).		
	Рубежный контроль		100
	Итоговый контроль		100

Модуль 1. Методологические основы научного знания

Семинар 1. Определение науки и научного исследования.
Будут даны основные понятия науки и научного мышления. Задачи, классификация и этапы становления науки. Определены основные категории науки. Дано понятие и разработка научной гипотезы. Эмпирические основы науки, теоретические основы и методологические основы.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:

1. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
2. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

1. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
2. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
3. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
4. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 2. Методология и классификация научных исследований.
Специальные методы, общенаучные методы. Методика исследования. Практическая компонента -гипотеза. Классификация научных исследований.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:

3. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
4. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.
Дополнительная литература:
5. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
6. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
7. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
8. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.
Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 3. Стандарты и требования к проведению научного исследования в области здравоохранения.

Научное исследование. Технология исследовательской работы. Понятие и этапы научного исследования. Формулировка темы, проблемы и цели исследования. Формирование гипотезы, методики и рабочего плана. Результат научного исследования: виды и требования.

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:
5. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
6. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.
Дополнительная литература:
9. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
10. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
11. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
12. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.
Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 4. Теоретические исследования.
Фундаментальные и прикладные исследования. Эмпирическое и теоретическое исследование. Виды теоретических методов исследования: абстрагирование , аксиоматический метод, анализ и синтез. Методы теоретического исследования: идеализация, индукция и дедукция, восхождение от отвлеченного к конкретному. В научной диссертации методами являются: создание библиографии, реферирование; конспектирование, аннотирование, цитирование.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература

Основная литература:

7. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
8. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

13. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
14. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
15. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
16. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 5. Экспериментальные исследования.
Основные составляющие и классификация экспериментов. Матрица планирования. План-программа. Цели и задачи. Критериии-упрощение, наглядность, точность и достоверность результатов исследования. Регрессионный анализ, однофакторные (парные) и многофакторные регрессионные зависимости. Аппроксимация. Факторный эксперимент. Постановка задачи. Формализация. Реализация модели. Естественные эксперименты. Искусственные эксперименты. Вычислительные эксперименты. Лабораторный эксперимент. Натурный эксперимент. Контролируемый и неконтролируемый эксперимент.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература

Основная литература:

9. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.

10. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

17. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
18. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
19. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
20. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Модуль 2. Структура научных публикаций и обработка данных.

Содержание научной статьи: Название. Аннотация. Ключевые слова. Введение Методы исследования. Результаты. Обсуждение. Заключение. Список литературы

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:

11. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
12. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

21. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
22. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
23. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
24. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 6. Подготовительный этап научно-исследовательской работы.

Определение терминов: научная проблема, научная тема, формулировка проблемы.

Выбор темы исследования, постановку цели и задач исследования, определение его объекта и предмета, выдвижение первичной гипотезы. фундаментальный или прикладной характер исследования. Научная значимость ожидаемых результатов исследования; актуальность заявленной темы исследования;результативность исследования; степень значимости результатов реализации исследования; имеющийся у исследователя или коллектива ученых научно-методический задел; степень новизны методов исследования (научный инструментарий); квалификация руководителя и коллектива исполнителей; количество публикаций в ведущих рецензируемых научных журналах, включенных в перечень ВАК РК; количество публикаций в научных журналах, входящих в различные международные системы цитирования («Social Sciences Citation» (SSCf), «Arts and Humanities Citation Index» (АНСГ) и др.); обоснованность объема финансирования для реализации проекта.

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:

13. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
14. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

25. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
26. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
27. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
28. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 7. Обработка результатов научного исследования.

Проверка документов (бланков инструментария) на точность, полноту и качество заполнения. добор пропущенных данных, т.е. проведение дополнительных опросов взамен забракованных. Уточнение программы обработки и анализа информации. Кодирование данных в соответствии с заранее разработанной программой (заданием, инструкцией).

Ввод первичной информации на электронные носители. Систематизация однородных величин, определение процентных значений, группировка, ранжирование данных по возрастанию или убыванию признака, вычисление средних арифметических, средних взвешенных и других значений, необходимых для сжатия информации, приведение в состояние, удобное для анализа. Оформление данных в виде аналитических таблиц, графиков, диаграмм с использованием различных способов, приемов, повышающих наглядность информации. Шкалы измерения.

Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:

15. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
16. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

29. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
30. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
31. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
32. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 8. Методы графической обработки данных.
Экспериментальные данные в виде таблиц, графиков, а также с помощью математических уравнений.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:

17. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
18. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

33. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
34. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
35. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
36. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы
www.cdc.gov

www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 9. Методика оформления результатов научного исследования в виде научной работы. Изложение результатов. Подход к интерпретации данных. Обобщение результатов и оформление выводов.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:

19. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
20. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

37. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
38. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
39. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
40. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 10. Роль науки в современном обществе.
Двигатель общественного прогресса. Принятие решений для проблем здравоохранения, отвечать потребностям общества и справляться с глобальными проблемами. Принимать решения в здравоохранении на основе достоверной научной информации. Прогнозирование. Моделирование. Решение проблем на пути к устойчивому развитию.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:

21. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.

22. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.
Дополнительная литература:
41. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
42. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
43. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
44. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.
Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Модуль 3. Основы этики в научных исследованиях.

Семинар 11. Основы научной этики. Нормы и нарушения.
Теоретические основы научной этики. Понятия этики и социокультурные предпосылки ее формирования. Особенности и проблемные вопросы этики научных исследований.
Задания
Цель занятия
Вопросы
Методические рекомендации
Рекомендуемая литература
Основная литература:
23. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
24. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.
Дополнительная литература:
45. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
46. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
47. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
48. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.
Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 12. Международные документы по регулированию научных исследований.

Регулирование биомедицинских исследований с участием человека, защита его прав и достоинств осуществляется в современных условиях благодаря международным документам, выступающим в качестве основы национальных стратегий и программ развития биоэтической службы: Международные этические руководящие принципы для исследований в области здоровья с участием людей (ВОЗ), «Всеобщая декларация прав человека» (ООН, 1948 г.); Хельсинкская Декларация» (ВМА, Генеральные Ассамблеи 1964, 1975, 1983, 1989, 1996, 2000,2002 гг.); Международное руководство по этике биомедицинских исследований с участием человека» (CIOMS, Женева, 1993 г.); Декларация по продвижению прав пациентов в Европе (ВОЗ, 1994 г.); Руководство по надлежащей клинической практике, подготовленное Международной конференцией по гармонизации (ICH GCP, 1996 г.); Конвенция о защите прав и достоинства человека в связи с применением достижений биологии и медицины, принятая Советом Европы (1997 г.) с последующими «Дополнительными протоколами.

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:

25. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
26. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

49. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
50. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
51. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
52. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 13. Доклинические исследования.

Основные понятия, ключевые определения, концепции. «Доклинические» или «предклинические»? Фармакодинамика, фармакокинетика и токсичность исследуемого вещества до его введения в человеческий организм, данные доклинических исследований. Уход за животными. Основные аспекты стандарта по химическим свойствам, процессу производства и контролю качества (Chemistry, Manufacturing, Control, CMC) учитываются в доклинических исследованиях.

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:

27. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
28. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

53. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
54. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
55. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
56. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 14. Клинические исследования. Этические нормы и принципы в клинических исследованиях.

Понятие, виды клинических исследований. Фазы клинического испытания. РКИ и не рандомизированные клинические испытания. Документация, СОПы, рандомизация, инспекция. Правила проведения клинических исследований лекарственных средств и медицинских изделий, клинико-лабораторных испытаний медицинских изделий для диагностики вне живого организма (in vitro) и требования к клиническим базам (in vivo). Выдача разрешения на проведение клинического исследования и (или) испытания фармакологических и лекарственных средств, медицинских изделий.

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:

29. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
30. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

57. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
58. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
59. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
60. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Семинар 15. Этические и правовые вопросы использования клинических исследований в уязвимых группах населения: дети, беременные женщины и больные с психическими расстройствами.

Конвенция по правам ребенка, предложенная ЮНИСЕФ и одобренная Генеральной ассамблеей ООН в 1989 г.. Права детей. Основные этические принципы: признание ценности и достоинства человеческой жизни, неукоснительное соблюдение старинного постулата «Не навреди», осознанное добровольное согласие участника исследования наряду с полным его информированием и соблюдение конфиденциальности. Осторожные и взвешенный подход к исследованиям в педиатрической практике.

Задания

Цель занятия

Вопросы

Методические рекомендации

Рекомендуемая литература

Основная литература:

31. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
32. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

61. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
62. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
63. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
64. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.

Электронные ресурсы

www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Основная литература:

33. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
34. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.

Дополнительная литература:

65. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.

66. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
67. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
68. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.
Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

Основная литература:
35. Основы научных исследований. Учебно-методическое пособие. А.Н.Огурцов.-Харковь.-2008.-178с.
36. Методология и методы научного исследования. Москва-Юрайт.-2017.-151с.
3. Биомедицинская этика. Практикум. ПРАКТИКУМ. Минск.- 2011.-204с.
Дополнительная литература:
69. Handbook for good clinical research practice (GCP) : guidance for implementation. WHO Library Cataloguing-in-Publication Data.-2005.-125 p.
70. Deni Elliot. Ethical Challenges: Building an Ethics Toolkit Authorhouse: 2008
71. Robert J. Spitzer, S.J., Ph.D. Ten Universal Principles: A Brief Philosophy of the Life Issues. Ignatius Press, 2011.
72. Thomas A. Shannon and Nicholas J. Kockler, An Introduction to Bioethics. 4th Edition. Paulist Press, 2009.
Электронные ресурсы
www.cdc.gov
www.who.org
www.medline
www.pubmed
www.cochranelibrary

	Strength and limitations. Practical work using scientific articles from websites as an example.		
Семинар 10	Bias and confounding factors in studies Overview of epidemiological studies. Practical work using scientific articles from websites as an example.	3	10
	Midterm exam.		100
Module III. Types of Epidemiology			
Семинар 11	Diagnostic and screening tests. Sensitivity and specificity of tests.	3	10
Семинар 12	Statistical methods in Epidemiology. Meta-Analysis. Practical work using scientific articles from websites as an example.	3	10
	MIWT 4. Consultation of masters' independent work carry out on topics 11-12.		
	MIW 4.Clinical Trial 1.		25
Семинар13	DEPTH model in Medicine. Implementation of epidemiologic studies in Medicine. Practical work using scientific articles from websites as an example.	3	10
Семинар 14	Exposure-Oriented Epidemiology: Occupational, Environmental, Nutritional, Radiation, Physical Activity Epidemiology .	3	10
	MIWT 5. Consultation of masters' independent work carry out on topics 13-14.		
.	MIW 5. Clinical Epidemiology and Evidence-Based Medicine.		25
Семинар 15	Outcome-Oriented Epidemiology: Infectious Disease Epidemiology, Cardiovascular Disease and Health, Cancer Epidemiology, Epidemiology of Diabetes, Epidemiology of Psychiatric Disorders.	3	10
.	MT 3		100
.	Final Exam		100

Module I. Bases and concepts of Epidemiology

Семинар 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 desicions.

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

Methodical recommendations: students should know Семинарification and criteria of Epidemiologic
studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

Семинар. 2. Concepts of Disease Occurrence. Natural History and Spectrum of Disease. Chain of Infection. Epidemic Disease Occurrence.
Conternt. A critical premise of epidemiology is that disease and other health events do not occur randomly in a populationA 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.
Tasks.
Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинарification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

5. www.PubMed

Семинар 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.
Tasks.
Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in
Methodical recommendations: students should know Семинapification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

Семинар 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. Tasks.

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

Purpose of Семинар: to form knowledge, practical skills and professional competencies in
Methodical recommendations: students should know Семинарification and criteria of Epidemiologic
studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

Семинар 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. Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинарification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

5. www.PubMed

Module П. Methodological approaches in Epidemiology

Семинар 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 answer what, when, where, when and how questions, but not why and how questions. Hypothesis is formed on base of 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.

Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинapification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.

Points for work performed are affixed in accordance with the syllabus.

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.

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

Семинар 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. Tasks.
Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинарification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

Семинар 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 expose 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 of exposition of risk factors. They were open and closed, retrospective and prospective. Evaluation and measurement of the occurrence of diseases. Measurement of expose 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. Tasks.
Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинарification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using in Medicine.
Points for work performed are affixed in accordance with the syllabus.
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.

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

Семинар 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. Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions.
Purpose of Семинар: to form knowledge, practical skills and professional competencies in
Methodical recommendations: students should know Семинарification and criteria of Epidemiologic
studies, deeply know descriptive study: aim, objectives, results, measurement and values of results,using 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.

Семинар 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. Tasks.

Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинарification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results, using 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.

Module III. Module III. Types of Epidemiology

Семинар 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. Tasks.

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

Purpose of Семинар: to form knowledge, practical skills and professional competencies in Methodical recommendations: students should know Семинарification and criteria of Epidemiologic studies, deeply know descriptive study: aim, objectives, results, measurement and values of results,using 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.

Семинар 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. PrinciplesofDataAnalysis, StatisticalThinking, MultivariateAnalysis, HandlingofDataProblems, 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. Tasks.

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

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

Methodical recommendations: students should know Семинарification and criteria of Epidemiologic

studies, deeply know descriptive study: aim, objectives, results, measurement and values of results,using 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.

Семинар 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. Tasks.

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

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

Methodical recommendations: students should know Семинарification and criteria of Epidemiologic

studies, deeply know descriptive study: aim, objectives, results, measurement and values of results,using 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.

Семинар 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, cardio-vascular diseases etc. Types of Exposure-Oriented Epidemiology are Occupational, Environmental, Nutritional, Radiation, Physical Activity Epidemiology. Tasks. Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in
Methodical recommendations: students should know Семинарification and criteria of Epidemiologic
studies, deeply know descriptive study: aim, objectives, results, measurement and values of results,using 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.

Семинар 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 of results of outcomes related with exposure determinants (reasons and risk factors). They are the major cause of burden:morbidity, mortality and disorders. Tasks. Discussion. Students in small groups answer to tasks, discuss and make desicions. Purpose of Семинар: to form knowledge, practical skills and professional competencies in
Methodical recommendations: students should know Семинарification and criteria of Epidemiologic
studies, deeply know descriptive study: aim, objectives, results, measurement and values of results,using 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 Ooffice of epidemiologic program СДС, 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.

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

Семинар 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 particip nts 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 Семинар: 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 СДС, 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.

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

Семинар 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 desicions.

Purpose of Семинар: 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.
6. Principles and methods of Epidemiology. 3-d Edition. R. Dicker Ooffice of epidemiologic program СДС, 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.

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

5. www.PubMed

Семинар 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 desicions.
Purpose of Семинар: 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 Ooffice of epidemiologic program СДС, 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.

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

Module П Analytical studies

Семинар 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 Семинар: 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 СДС, 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.

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

Семинар 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 Семинар: 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.
6. Principles and methods of Epidemiology. 3-d Edition. R. Dicker Ooffice of epidemiologic program СДС, 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.

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

Семинар 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 Семинар: 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.
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 СДС, 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.

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

Семинар 9. Exposure or outcome. Measurement of expose 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 desicions. Purpose of Семинар: 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
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 СДС, 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

Семинар 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 desicions. Purpose of Семинар: 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.
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 СДС, 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

Module III. Experimental studies

Семинар 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 desicions. Purpose of Семинар: 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
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 СДС, 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

Семинар 12. Design of clinical trials (phases, safety and effectiveness of drugs). Algorithm of clinical trial.

Content. Clinical trials for drug development are Семинарically 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 dosefinding 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 desicions.
Purpose of Семинар: 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.
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 СДС, 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

Семинар 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 Семинар: 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
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 СДС, 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

Семинар 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 desicions. Purpose of Семинар: 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 Ooffice of epidemiologic program СДС, 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.

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

Семинар 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, researches 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 desicions. Purpose of Семинар: 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.
6. Principles and methods of Epidemiology. 3-d Edition. R. Dicker Ooffice of epidemiologic program СДС, 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