KHARKIV NATIONAL MEDICAL UNIVERSITY



DESIGN OF EPIDEMIOLOGICAL STUDIES

Methodical developments

for teachers to conduct a practical lesson

on the course ***“Social medicine, public health (biostatistics)”***

for students in the specialty:

– 222 “Medicine”

– 228 “Pediatrics”,

– 221 “Dentistry”.

Kharkiv

2019

MINISTRY OF PUBLIC HEALTH OF UKRAINE

KHARKIV NATIONAL MEDICAL UNIVERSITY

DEPARTMENT OF PUBLIC HEALTH AND HEALTHCARE MANAGEMENT

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*Затверджено вченою радою Харківського національного медичного університету.*

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Design of Epidemiological studies: methodical developments for teachers to conduct a practical lesson on the course “Social medicine, public health (biostatistics)” for students in the specialty 222 “Medicine”, 228 “Pediatrics, 221 “Dentistry” / V.A. Ognev, I.A. Chukhno, G.V. Lisova, I.S. Bielievtsova. – Kharkiv : KhNMU, 2019. – 32 p.

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**GUIDELINES FOR TOPIC TRAINING**

The aim of the class: get acquainted with the basics of epidemiological research design (case-control, cohort, randomized controlled trials), the concept of the “gold standard”.

Need to know:

* ***program questions:***
* concept of modern epidemiology;
* classification of epidemiological studies;
* comparative characteristics of different types of research, assessment of evidence and their results;
* design of epidemiological studies: empirical/observational and experimental studies;
* retrospective and prospective studies;
* empirical/observational studies (descriptive and analytic);
* descriptive epidemiology: description of a single case and a series of cases;
* analytic epidemiological studies: case-control, cohort, randomized controlled trials;
* concept of randomization and stratification;
* the gold standard of research;
* ethics of research;
* types of design;
* types of control;
* “blindness” of the study;
* required sample size;
* the choice of object and unit of study;
* inclusion and exclusion criteria.

**Need to be able to:**

– to formulate the design of the epidemiological study and apply the main methods of epidemiology when the problems of public health are studying.

**The form of the lesson**: a practical lesson.

**Location**: classroom of the department.

**Methodical support of the lesson:**

* methodical guidelines to classes;
* guidance literature: student’s workbook (basis preparation);
* presentation materials;
* summary of lectures;
* tasks for test.

**The algorithm of the class:** After verifying presence of students teacher announces topic and goal of class, explains relevance of it’s study and ability to use in practice.

Using educational materials provided by teacher students learn material on their own topics and perform specified tasks. At the end of class teacher will ask student what issues have arisen in preparation of topic and helps to ensure a sufficient understanding of them. Then teacher moves to control students' knowledge on basic theory material.

*Applicable forms of control:* oral questioning of students, theoretical or problematic discussion, prompt controls on options-time to complete 5–7 minutes, daily control of theoretical knowledge – individual tasks or task for several options, including 3–4 theoretical questions (time to complete not more than 20 min.), execution of tests followed by analysis of answers.

After control of theoretical knowledge teacher makes general conclusion on studied subject, sums up control of theoretical knowledge of students, as well as announcing to students their received assessment and homework.

**Plan of the lesson timing duration of occupation percentage:**

|  |  |  |
| --- | --- | --- |
| 1 | Introduction into class | up to 5% |
| 2 | Studying of key themes and issues control of theoretical knowledge | 90% |
| 3 | Summarizing and announcement homework theoretical knowledge | up to 5% |
|  | **Total** | 100% |

**Recommended literature**

**Basis literature**

1. Біостатистика / за заг. ред. чл.-кор. АМН України, проф. В.Ф. Москаленка. – К. : Книга плюс, 2009. − С. 12-31.

2. Социальная медицина и организация здравоохранения / под общ. ред. Ю.В. Вороненка, В.Ф. Москаленко. – Тернополь : Укрмедкнига. 2000. –
С. 23-32.

3. Социальная гигиена и организация здравоохранения / под ред. Н.Ф. Серенко, В.В. Ермакова. – М. : Медицина, 1984. – С. 102-104.

4. Тестовые задачи по социальной медицине, организации здравоохранения и биостатистике : учеб.пособ. для студентов мед. ф-тов / под ред. В.А. Огнева. – Харьков : Майдан, 2005. – С. 9-14.

5.Лекционный курс кафедры.

**Additional literature**

1. Альбом А. Введение в современную эпидемиологию / А. Альбом, С. Норелл. – Таллинн, 1996. – 122 с.

2. Власов В.В. Введение в доказательную медицину / В.В. Власов. – М. : Медиа Сфера, 2001. – 392 с.

3. Герасимов А. Н. Медицинская статистика / А.Н. Герасимов. – М. : ООО «Мед.информ. агентство», 2007. – 480 с.

4. Зайцев В.М. Прикладная медицинская статистика / В.М. Зайцев, В.Г. Лифляндский, В.И. Маринкин. – СПб. : ООО «Изд-во ФОЛИАНТ», 2003. – 432 с.

5. Общая теория статистики: учебник / под ред. чл.-корр. РАН И.И. Елисеевой. − 4-е изд., перераб. и доп. − М. : Финансы и Статистика, 2000. − 480 с.

6. Основы доказательноймедицины / под ред. М. П. Скакун. – Тернополь : Укрмедкнига, 2005. – 244 с.

7. Реброва О.Ю. Статистический анализ медицинских данных. Применение пакета прикладных программ STATISTICA / О.Ю. Реброва.–М. : Медиа Сфера, 2002. – 312с.

8. Сергиенко В.И. Математическая статистика в клинических исследованиях / В.И. Сергиенко, И.Б. Бондарева. – М. : ГЭОТАР-МЕД, 2001. – 256 с.

**Information resources**

1.Население Украины. Демографический ежегодник. – К. : Госкомстат Украины –[www.ukrstat.gov.ua](http://www.ukrstat.gov.ua/)

2.U.S. National Library of Medicine –Национальная медицинская библиотека США– <http://www.nlm.nih.gov/>

3.Государственная научно-педагогическая библиотека Украины им. В.О. Сухомлинского–<http://www.dnpb.gov.ua/>

4.Научная библиотека Харьковского національного медицинского университета – <http://libr.knmu.edu.ua/index.php/biblioteki>

5.Научная педагогическая библиотека им. К.Д. Ушинского Российской академии образования – <http://www.gnpbu.ru/>

6.Национальная библиотека Украины им. В.И. Вернадского –<http://www.nbuv.gov.ua/>

7.Национальная научная медицинская библиотека Украины –<http://www.library.gov.ua/>

8.Харковская государственная научная библиотека им. В.Г. Короленка – http://korolenko.kharkov.com

9.Центральная библиотека Пущинского научного центра РАН –<http://cbp.iteb.psn.ru/library/default.html>

10.Центральная научная медицинская библиотека Первого Московского государственного медицинского университетаим. И.М. Сеченова–<http://elibrary.ru/defaultx.asp>

**BASIC THEORETICAL MATERIAL**

**FOR PREPARATION FOR THE LESSON**

**1. Epidemiology as a science**

Epidemiology is the basis of preventive medicine and a source of information for public health activities. The term “**epidemiology**” comes from the Greek words “*epi*”, which means “on” or “above”, “*demos*” – “people” and “*logos*” – “science”. Thus, epidemiology is the science about “what is common among the people, what is happening to the people”. In modern terminology, ***epidemiology is the study of the prevalence and determinants of health-related conditions or events in specially defined populations for managing and controlling health problems***.

At the same time, *prevalence* means analysis in time, at a place, according to selected groups, according to individual characteristics of the population that has been studied.

*Determinants* are the physical, biological, social, cultural, and behavioral factors that affect health.

*Health-related* conditions and events include illness, deaths, behaviors, reactions to preventive measures, and the organization and use of health services.

*A specially defined population* is a group with a precisely defined trait and number of people.

*Management and control* are the ultimate goals of an epidemiological approach to health care – to strengthen, protect and restore health.

Nowadays epidemiology is not actually medical science but the main science of the field of research and practice, called *“public health”.*

Epidemiology is often associated only with epidemic diseases but this is wrong. The problem is that, initially, the main problem for the population’s health was precisely infectious diseases, which is why epidemiology has dealt with epidemic processes. But since the middle of the 20th century, non-epidemic diseases have become the main population’s health problem. Epidemiological research methods have been applied to the study of any diseases and conditions of a massive nature, including those caused by physical and mental, social and other factors.

Currently, ***general epidemiology*** includes various sections. For example, epidemiology of epidemic (infectious) diseases, epidemiology of non-epidemic diseases, clinical, field epidemiology, etc.

The epidemiology of non-epidemic diseases differs from infectious epidemiology by a number of significant features of a quantitative nature. There are:

* as a rule, the latent period of non-infectious diseases is much longer than of infectious. And their specific term is unpredictable;
* a chronic disease develops gradually and its symptoms can vary over a wide range in the examined individuals. This increases the likelihood of misdiagnosis;
* for non-infectious diseases, a multifactorial nature of etiology and pathogenesis is typical. The dominant factor is clearly absent;
* in contrast to infectious epidemiology, it is impossible to clearly identify the impervious part of the population and to establish whether the absolute resistance of a specific person to a certain chronic non-infectious disease;
* prognoses of morbidity and effectiveness of preventive measures are probabilistic in nature and are justified in relation to the population as a whole.

**2. Goals and objectives of epidemiological research**

Epidemiological studies may have different goals and objectives. They can be: the study of morbidity, the development of various concepts in health care, directions, preventive programs to combat the spread of certain diseases or their groups, etc.

**The first task** of epidemiological studies, as a rule, is a description of the incidence of the population (*descriptive study*). It is impossible to perform subsequent tasks of epidemiological studies without a qualitative description of the problem. Descriptive epidemiology *provides a comparative description of the morbidity*. The main descriptive information includes information about “which disease occurs more often and which less often,” “when people get sick more often, and when less often”, “in which territory (where) they get sick, and where less frequent”, “which groups of the population are sick more often, and which less often”, etc.

In epidemiological studies, the description of the morbidity is carried out in order to obtain new or confirm poorly studied data, reflecting the natural manifestations of the morbidity in the population.

**The second task** of epidemiological studies is called ***analytic***, and the study itself is analytical. This task gives answers to the questions: *why* this disease occurs more often than others, *why* in this area, the risk of the disease being studied is higher than on another, *why* at this time people get sick more often than in other periods, etc.

In other words, to perform an analytical task, it is necessary to establish and evaluate *a causal relationship* between the perceived risk factors of the host and the environmental risk factors and the incidence of disease that were identified during the description.

The next task of epidemiological research is to study ***the causes of the emergence and spreading of diseases***. However, in epidemiological studies most often only reveal *the causal relationship* between the morbidity and the alleged cause.

For example, epidemiological studies conducted in different countries have been conclusively proved that cigarette smoking is one of the risk factors for lung cancer. However, the question: “Why does cigarette smoking dramatically increase the risk of lung cancer?” cannot be solved epidemiologically.

***The prognosis of morbidity*** is also the task of many scientific epidemiological studies. The quality of the prognosis (*especially short-term*) depends primarily on the quality of the retrospective description of the incidence, i.e. from the accuracy of estimates of the natural and accidental in the process of the spread of the disease among the population of a particular territory for a certain period. However, the ability to predict possible, unusual (*in relation to the past*) changes in the activity of biological, social, and climatic factors, which constitute a complex of reasons determining various manifestations of the incidence, has no less significance for prognostic estimates of morbidity.

Modern tasks of epidemiology are the identification of ***priority problems in the field of public health*** and *the* ***development of measures to eliminate*** *or minimize the effect of adverse factors.*

One of the important tasks of epidemiological research is ***to assess the quality and effectiveness*** of all that is used or proposed to be used to protect public health. Epidemiological studies assess the *potential efficiency* of the proposed preventive, diagnostic and therapeutic measures, diagnostic tests, etc.

**The International Epidemiological Association** (WHO, 1986) has formulated the main tasks facing the epidemiology of non-infectious diseases, they are:

* studying the prevalence and natural course of certain diseases by population groups, identifying the extent of the problems associated with these diseases;
* identification of factors of the external and internal environment that contribute to or impede the emergence and spread of these diseases;
* identification of priority problems in the field of public health;
* development of measures to eliminate or minimize the effect of adverse factors. Study of the effectiveness of preventive and therapeutic measures.

**3. Design of the epidemiological research**

The *design of the epidemiological research* meansall the features of a specific study envisaged by its plan (*design* = plan). These features are expressed by numerous methods of epidemiological research, as well as their various combinations, which characterizes the types of design and its diversity. For example, design of cohort studies, design of case-control studies, design of cross-sectional (single-step and environmental (correlation)) studies. The “*gold standard*” of the clinical study is ***randomized controlled double-blind trial***, etc.

Epidemiology, like any science, has special research methods. In modern epidemiology, ***epidemiological methods*** are understood as “tools” of studying the patterns of the spreading of diseases and other conditions among the population, based on the use of statistical indicators.

The materials of the WHO Regional Office for Europe (International Symposium on the Teaching of Epidemiology, 1967) note that in accordance with the objectives, at least three types of epidemiological studies can be distinguished:

* *research related to the study of the distribution of a disease or illnesses among a certain population (****descriptive epidemiology****);*
* *research related to the study – using a retrospective and prospective study – hypotheses formulated to explain the results of observations which were made (****analytic epidemiology****);*
* *research related to the use of the experiment and aimed at determining the effect of control tests for managing exposure to harmful conditions, or* – *the effect of preventive measures among the population (****experimental epidemiology****).*

However, this classification of epidemiological studies *cannot independently reflect all the design features of a particular study, since their options are much larger.*

Most likely, it is necessary to focus on the specific epidemiological method when the design of a study is described. The most complete description and description of the methods that form the design of an epidemiological study is provided by the authors (*V. Lekhan, Y. Voronenko, O. Maksimenko, and others, 2005*) in the textbook “*Epidemiological methods for studying non-infectious diseases*.”

This classification of methods is carried out using different criteria. It provides the following separation:

1. **Depending on the purpose**, epidemiological studies are divided into:

* *search* (hypothesize);
* *testing the hypothesis*.

2. **According to the nature of the intervention**, epidemiological methods can be (Fig. 1):

* + *empirical (empirical research methods)*, or observational studies (*observational studies*) are the research methods without interfering with the natural course and development of the disease (observation, measurement, comparison).
	+ *experimental* *(experimental or interventive epidemiology)* – research methods in which the researcher makes changes intentionally, the effects of which are observed, measured, compared. The experiment allows the scientist to control all factors that may affect the phenomenon under study.

Also **empirical or observational** methods include:

* + *descriptive* (description of individual cases and description of a series of cases);
	+ *analytic studies* (cohort, case control and environmental).

**Experimental** include (*experimental or interventive epidemiology*):

* *field/community;*
* *clinical.*

*Field and clinical* can be controlled and uncontrolled, and controlled ones – randomized and non-randomized.

From the point of view of **the duration of observation**, epidemiological methods can be distinguished (Fig. 2):

* + *single-stage studies* or transverse, or cross-sectional;
	+ *dynamic* or longitudinal studies, which may be cohort, experimental and case-control.

Depending on the dynamics of the study, *short-term studies (short term)* are distinguished from dynamic or longitudinal methods for up to 3 years and long-term studies for more than 3 years, while the first and second are divided into retrospective (case-referent study, case-control study, case-history study, retrospective study) and prospective (cohort study, follow study, prospective study) (Fig. 3).

As a result, numerous results of epidemiological studies were the basis for the development of a new section of medicine – the so-called **evidence-based medicine**.

It should be noted that a large number of classifications are given in the literature describing epidemiological methods.

There are a lot of methods and their variants and it is difficult to cover them, in connection with which we present various variants of research design (Table 1).

Epidemiological research methods

Empirical/observational

Experimental

Descriptive

Analytic

Case description

Description

case series

Cohort

Case control

Ecological

Field

Clinical

Controlled

Uncontrolled

Non-randomized

Randomized

Figure 1. Classification of epidemiological research methods by type of intervention

Table 1

**Possible “Design” of epidemiological studies**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Terms characterizing specific features of the epidemiological study** | Descriptive | Empirical, observational,  | Case control | Cohort | Randomized clinical trial | Randomized field research | Population | Sample | Retrospective | Prospective | Momentary | Dynamic | Field |
| Descriptive  |  | **+** | **–** | **–** | **–** | **–** | **+** | **+** | **+** | **–** | **+** | **+** | **+** |
| Empirical, observational, observational | **+** | **–** | **+** | **+** | **–** | **–** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| Case control | **–** | **+** | **–** | **–** | **–** | **–** | **+** | **+** | **+** | **–** | **–** | **–** | **+** |
| Cohort | **–** | **+** | **–** | **–** | **–** | **–** | **+** | **+** | **+** | **+** | **–** | **+** | **+** |
| Randomized clinical trial | **–** | **–** | **–** | **–** | **–** | **–** | **–** | **+** | **–** | **–** | **–** | **–** | **–** |
| Randomized field research | **–** | **–** | **–** | **–** | **–** | **–** | **–** | **+** | **–** | **–** | **–** | **–** | **+** |
| Population | **+** | **+** | **+** | **+** | **–** | **–** | **–** | **–** | **+** | **+** | **±** | **+** | **+** |
| Sample | **+** | **+** | **+** | **+** | **+** | **+** | **–** | **–** | **+** | **+** | **+** | **+** | **+** |
| Retrospective | **+** | **+** | **+** | **+** | **–** | **–** | **+** | **+** | **–** | **–** | **–** | **+** | **+** |
| Prospective | **–** | **+** | **–** | **+** | **–** | **–** | **+** | **+** | **±** | **–** | **–** | **+** | **+** |
| Single-stage | **+** | **+** | **–** | **–** | **–** | **–** | **±** | **+** | **–** | **–** | **–** | **–** | **+** |
| Dynamic | **+** | **+** | **–** | **+** | **–** | **–** | **+** | **+** | **+** | **+** | **–** | **–** | **+** |
| Field | **+** | **+** | **+** | **+** | **–** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **–** |

 Epidemiological studies

Momentary (transverse)

Dynamic (longitudinal)

Cohort

Experimental

Case control

Figure 2. Classification of epidemiological studies of the duration of observation

Longitudinal epidemiological studies

Prospective

Retrospective

Cohort

Experimental

Case control

Figure 3. Classification of longitudinal epidemiological studies

**4. Population and sample
epidemiological studies, their features**

**Population studies** are conducted in the scope of the *general population*. In the general case, a population denotes an object of observation, representing the totality of all observation units with certain characteristics. They are often called signs of inclusion / exclusion in the population. As has been repeatedly noted, in epidemiology, these signs refer to signs of time, place, and “face” The idea of conducting a population research is connected with the desire to obtain comprehensive information about the phenomenon being studied.

The main drawbacks of continuous research are the large expenditures of time, effort and resources, and often the impossibility to conduct them.

To overcome the drawbacks of population studies, help sample research, which is the main special tool of many sciences.

**Sample studies** are designed to draw conclusions about the characteristics of the studied phenomenon in the entire population (general population). This sample is based on data obtained from studying the morbidity of a relatively small part of the population – the sample was formed. Thus, the purpose of sample studies is to receive representative *(from lat. Represento* – *present)* information that could be extrapolated to the entire population. The representativeness of the sample is provided by:

* + the required number (volume, size) of the sample;
	+ adherence to the principle of *randomization*.

The sample size depends on many components and, above all, on the nature of the study. If the purpose of the study is to estimate the incidence among the population, then it is necessary:

* + to establish the degree of reliability of measuring incidence, i.e. the magnitude of the possible deviation of sample data from the study population data;
	+ approximately know the prevalence of diseases among the population.

**If the population size is unknown**, the sample size is calculated by the formula:

$n=\frac{t^{2}×\left⟨I×q\right⟩}{Δ^{2}}$ (1)

**If we know the population size**, the sample size is determined by the formula:

$n=\frac{I×q×t^{2}×N}{\left⟨N×Δ^{2}\right⟩+\left⟨I×q×t^{2}\right⟩} $(2)

Denote:

n – is the desired sample size;

N – is the population size;

t – is the reliability criterion (most often equal to 1.96 ≈ 2);

I – estimated frequency of the disease;

q = (R–I) where, R is the used dimension of the indicator I;

∆ – selected maximum permissible error of the indicator. Usually the maximum permissible error is no more than 25% of the value of the indicator (I).

**An example of determining the sample size.** *Suppose that in the city of N it is planned to conduct a one-stage selective study in order to study the frequency of new cases of arterial hypertension among men 20–29 years old. The number of this population in the city of N. is 15400. It is known that the frequency of new cases of arterial hypertension in this group of men in the city of N. is 70*‰ *(I = 70*‰*). Therefore,* ∆ *will be 25% of 70.0, ie:* ∆ *= (25x70.0) / 100 = 17.5,* ∆2 *= 306.2*‰

*n = (70.0x (1000-70.0) x2*2*x15400) / (15400x306.2) + (70.0x (100-70.0) x2*2*) =*

*= 806 people.*

*Thus, to obtain sample data corresponding to the required accuracy of 15400 men 20–29 years old, 806 people should be examined.*

The second condition for achieving representativeness of the sample is the adherence to the principle of randomization (Random = case). Randomization provides random selection of a sample of individuals representing the general population.

The main purpose of a randomized study is to eliminate any bias or bias in the evaluation of the compared methods.

This can be achieved by:

* *random, unintended distribution of patients into groups*: if the number of patients is large, then it can be assumed that *the intervening factors* are distributed randomly in both of the observed groups and will be mutually eliminated (neutralized, redeemed);
* *tracking the results of applying the studied methods* in all patients included in the research (which allows us to study not only the results of using the method, but also the reasons for refusing treatment or the impossibility of its completion);
* *“blind” assessment of the results* when the researcher does not know which group the patient was included in; *double “blind*” method, when the patient also does not know in which group – experimental or control – he will be included; *the triple “blind” method*, when apart from the patient, the researcher, but the statistician does not have this information;
* *a clear definition of the final stage* or the result of the study (for example, five-year survival, postoperative mortality) – this eliminates the possibility of a double interpretation of the data obtained.

In this case, ***randomization gives an equal chance*** to each unit of observation from the general population to get into the sample or group, which reduces the risk of inadvertent distortion of the composition of the sample or group.

The implementation of the principle of randomization is provided by various ways of sampling. The choice of method depends on the study design, the expected accuracy of the results, the volume of the general population, the possibility of using the most accurate method and other objective and subjective reasons.

*Currently, the ideal method of randomization is considered to be the use of random numbers, or similar computer programs for sampling units of observation*. This method provides random, non-repetitive selection, in which the observation unit is selected from the population only once. This method of randomization is mandatory for the formation of *the main and control groups during the majority of clinical randomized trials*, which contributes to the adherence to the principle of impartiality of the study and minimizing unintentional distortion of the group composition. This, in turn, provides reliable conclusions if the design of the research is respected.

Randomization equalizes the likelihood of exposure to the patient, not only those factors that are supposed to affect the prognosis, but also those that the researcher does not know about. Due to the random distribution of the differences between the two groups disappear and, thus, the likelihood of systematic errors in clinical studies due to differences in groups on any grounds. Randomization protects against incorrect conclusions regarding prognostic factors.

Randomized controlled trials are **the “golden” quality standard of scientific research**. The highest accuracy of the test results is achieved only in the case of a well-planned randomized study, which allows you to determine which method of diagnosis or treatment is the best. However, it should be remembered that no design can completely eliminate the researcher's bad faith.

**5. Empirical and observational methods
 of the epidemiological studies**

**Empirical** *(empirical research methods)*/**observational** *(observational study)* research does not involve intervention in the natural process of the emergence and spread of disease. The researcher observes and records the necessary information in accordance with the research program. Empirical research, in turn, can be **descriptive** and **analytical**.

**Descriptive** study provides descriptive epidemiological data, i.e. data on the incidence of morbidity. Such a study may be independent, but new descriptive epidemiological data obtained in it encourage the same or other researchers to continue the study in order to explain the identified manifestations of the incidence. Therefore, most often, a descriptive study is only the first part of a full-scale epidemiological study, necessarily including the analytical part.

A variety of descriptive studies for rarely encountered diseases are studies such as “description of individual cases” and “description of a series of cases”.

*Case report* is the oldest method of medical research: it describes in detail the data obtained by observing one or several cases of diseases *(no more than 10 patients)*. This method allows you to attract the attention of physicians to new or little-known diseases, manifestations or combinations of diseases; used to describe unusual manifestations of disease and is the only way to report a rare clinical event. The method is also a rich source of hypotheses about pathogenesis, risk, prognosis and treatment.

The task of investigating the “case report” type may pose a problem to the medical community and encourage more evidence-based research. Due to the descriptions of cases, congenital deformities were first identified due to the admission of thalidomide during pregnancy by the expectant mothers, fetal alcohol syndrome, toxic shock, etc.

*Case series* – a study that usually includes descriptive statistics of a group of diseases (the number of groups with a specific disease is *10 patients or more*). A series of cases – the most common way to describe the clinical picture of the disease. It is quite informative and convenient for this task, but has serious limitations. The drawbacks of the studies of a series of cases are the absence of a comparison group and the study of cases at different points in time and at different stages of the course of diseases.

*Analytic study* is dedicated to identifying the causes of the emergence and spread of diseases. The goal of analytical methods is, ultimately, to test a hypothesis (which is often formed in a descriptive study) of various specific etiological “impact-disease” links.

The search process corresponds to the general scientific understanding of two techniques *(directions)* of identifying causal relationships between the alleged cause and effect. The first method is “from the investigation to the cause”. When using it, *“pushing off”* from the resultant investigation (for example, illness) they are trying to find events in the past that could be considered as the causes of this effect. Another “from cause to effect” technique is when, focusing on the effect of the supposed cause, a causal effect is expected.

Analytical epidemiological studies are conducted using a set of original methodological approaches *(cohort studies, “case-control”)*, based on the use of special indicators and including special schemes for collecting and processing information.

***Case-control study*** – an analytical retrospective study, the purpose of which is to identify risk factors of the studied disease. The main group is selected from patients with the studied disease, the control group consists of healthy individuals. The fact of the impact of the studied risk factors is determined by interviewing individuals of the compared groups, their relatives, according to archival data. Comparison of the frequency of occurrence of individual factors in the main and control groups allows to calculate the odds ratio (OR) indicator, by the value of which, the presence of a causal relationship is estimated.

***A cohort study*** is an analytical study in which the term “cohort” *(cohorta)* means a group of people united by some common attribute and observed for a certain period of time to determine what happens to them in the future.

When conducting a study, the cohort includes people who do not have the disease under study, but may show up later. For example, in the study of the risk factor of gastric ulcer, all persons included in the cohort should not suffer from stomach diseases.

A cohort study makes it possible to assess the relative risk (RR) of the occurrence (spread) of a disease associated with suspected risk factors. Cohort studies are the best replacement for a true experiment in a situation where an experiment is impossible. *Follow-up* studies are conducted as prospective.

*The disadvantage of the cohort method* is:

* the number of persons included in the study should be significantly greater than the number of patients with the disease being studied, and therefore this method is not applicable for rare diseases;
* high cost of research due to the fact that it is necessary to examine a large number of people for a long time;
* the results remain unknown for a long time;
* allows you to assess the relationship between the disease and the impact of a relatively small number of factors (those that were identified at the beginning of the study).

Case-control and cohort studies are alternative methods for assessing risk factors.

Table 2

**Comparative characteristics**

**cohort and case-control studies**

|  |  |
| --- | --- |
| **Cohort study** | **Case-control study** |
| Starts by identifying a population exposed to a risk factor | Population exposed to a risk factor is not necessarily defined |
| Cases are not selected, but are established in the process of continuous observation (presumably all cases) | Cases are selected by the researcher from the available set of patients |
| The control group (without the disease under study) is not selected, but is formed naturally | The control group is selected by the researcher in such a way that it is similar to the experimental group |
| Impact is assessed before the disease develops | The impact factor is assessed and restored by memory after the development of the disease |
| Risk or incidence as well as relative risk are measured directly | The risk or incidence cannot be measured directly: the relative risk of exposure can be estimated by the odds ratio |

***A variety of analytical studies*** *are* ***ecological studies*** (they are also called territorial), the unit of analysis in which is the population or its subgroup, which is then attached to a geographical area. The purpose of these studies is to study the prevalence and causes of a disease in different geographic regions due to the characteristics of each region.

*This approach is justified in the following cases:*

* + when regional peculiarities are determined quite simply, in contrast to the complexity or high cost of their determination in individuals;
	+ to obtain a greater diversity of the studied features (for example, comparison of certain eating habits in international studies);
	+ when the accuracy of the overall measurement looks higher than the individual (for example, determining the level of alcohol consumption);
	+ when population measurements are the primary interest to the researcher (for example, the frequency of smoking cessation).

***A retrospective study*** is based on the study of information about incidents of morbidity for a period of time in the past, using the first method of searching for causal relationships – “***from investigation to cause”***. The main source of information is the existing system of registration and registration of patients. Retrospective research can be *descriptive and analytical*.

***A prospective study*** provides for the study of information as new (fresh) cases of the disease appear that did not exist at the beginning of the study. The study of cause-effect relationships is based on another technique – “from cause to the consequense”. The study is based on the likelihood of the occurrence of new cases of the disease (consequence) among the population group exposed to the risk factor (cause). Prospective studies are always analytical studies.

***Cross-sectional*** studies can be conducted both as descriptive and analytical studies. Apparently, therefore, in various epidemiological publications, they are referred to as descriptive, then as analytical studies. However, the main goal of these studies is to obtain information on the incidence of a disease in a population over a limited period of time, and, if it is necessary, such studies can be repeated. Since a cross-sectional study provides for the identification of all cases of the disease that exist at the moment, it is also called the “*prevalence study*”, and the results of a one-time study are often expressed in terms of moment prevalence. If the identified cases are associated with an effect, any risk factor can be analytical.

*A* ***dynamic*** *(longitudinal)* study provides for the systematic study of information on the incidence of the same population group. In this case, the study may be continuous or repeated for short intervals. Dynamic studies can be *short-term* lasting up to *3 years and long-term*, more than 3 years. Most often they are conducted as a *prospective (cohort study, follow study) or a retrospective (case-referent study, case-control study, case-history study)*.

As already mentioned, none of the methods and terms can describe all the features of an epidemiological study independently.

For example, the investigation of an outbreak of a disease is not only observational, but also analytical, most often continuous, one-time, retrospective or combined, clinical or field research.

**6. Experimental epidemiological studies**

***Experimental***study provides for ***controlled and reproducible intervention*** in the natural development of morbidity in order to identify its causes. At the same time, the epidemiological experiment must fully comply with other general scientific requirements. In this connection, the terms *“natural”*, *“uncontrolled epidemiological experiment”* used by some authors are incorrect. Since the experiment answers the question “why it happened as described in the experiment,” any experimental study is always analytical.

***Uncontrolled and controlled research.*** When developing new methods of treatment and prophylaxis, on the one hand, promising ideas are required, on the other hand, ways to reliably verify them. Two main types of research can be used to evaluate new methods: **uncontrolled and controlled.**

This is due to the fact that some methods of treatment and prophylaxis act so quickly and efficiently that their value is obvious even without formal verification, and there is no need for a thorough, rigorous test procedure. In this case, it is easy to prove the effectiveness of the method by evaluating the results in only one group of patients without comparison with the control one. This research method is called **uncontrolled clinical research** and can be used only in exceptional cases.

For example: *doctors have no doubts about the effectiveness of vaccination for certain infectious diseases, antibiotics for purulent-septic conditions, surgery for appendicitis, and insulin for diabetes mellitus. In these cases, not only is there no need to form control groups, but this is also incorrect, since patients in the control group are at risk of life.*

At the same time, most of the proposed new methods of prevention, diagnosis and treatment have a not so impressive effect. As a rule, the new technique allows only a few percent to increase the clinical effect, which makes it difficult to objectively identify it. In these cases, in order to avoid mistakes, thin and sensitive approaches are needed, among which are **controlled methods** of research (the presence of a control group is mandatory).

Thus, the most optimal design of an epidemiological experiment is randomized controlled trials in two variants – clinical and field.

Randomized clinical controlled trial is a special type of cohort studies, the conditions for which (selection of intervention groups, the nature of the intervention, the organization of observation and evaluation of outcomes) ensure the elimination of systematic errors. In terms of controllability, clinical trials surpass conventional cohort studies. In essence, this is an experiment similar to that conducted in the laboratory. With the classical scheme of controlled clinical research in the experiment, two appropriately selected groups (samples) are used, of which only one is exposed to the experimental factor (a new method of treatment, prevention).

Although the term ***“clinical”*** is associated with the site of an epidemiological study, it is used only to refer to research conducted in the ***clinic*** to assess the potential effectiveness of therapeutic drugs, diagnostic methods, and patient regimens. Such studies are called ***randomized controlled clinical*** trials.

***A randomized field controlled study is an experimental study***, in the field, of the potential effectiveness of any means (methods) that prevent the occurrence of diseases.

*Field* is considered a study conducted outside of medical institutions. Its scope can be quite varied: from a small outbreak investigation to a nationwide survey. Field research can be descriptive, analytical, observational and experimental, continuous and selective, retrospective and prospective, one-time and dynamic.

***The conditions that provide randomization in the study include:***

* random, unintentional distribution of patients into groups: if the number of patients is large, it can be assumed that additional factors, distributed in both observed groups in a random way, will be mutually eliminated (neutralized, redeemed);
* tracking the results of the intervention in all patients included in the study (which allows to study not only the results of this intervention, but also the reasons for the refusal of treatment or the impossibility of its completion);
* “blind” assessment of results. (The types of “blinding” include: open research, when all participants (patient, researcher, statistician, staff of diagnostic services) are aware of the formation of observation and intervention groups; simple blinding, when the patient does not know which observation group he is in (main or control ); double blindness, when not only the patient, but also the researcher is also not aware of the results of the inclusion of patients in the first or second groups; triple blindness, when in addition to the patient and the researcher he does not know this information and statistics Conducting statistical analysis of these groups, the full dazzle, except when the patient, researcher, statistician, not yet aware of this information and the staff of diagnostic services);
* a clear definition of the final stage or the result of the study (for example, 5-year survival rate, postoperative mortality) – this eliminates the possibility of a double interpretation of the data obtained.

**7. Epidemiological methods as successive stages
the process of studying the patterns of the diseases**

Studies conducted using epidemiological methods can be considered as successive stages of the process of studying the patterns of the emergence and spread of non-infectious diseases.

Table 3

**Optimal research methods**

**in relation to various issues of medicine and health**

|  |  |
| --- | --- |
| **Question** | **Research method** |
| Prevalence | Descriptive, one-step research |
| Frequency of occurrence of new cases (diseases, their consequences) | Analytical, cohort studies |
| Risk | Analytical, cohort, case-control studies |
| Forecasting | Cohort studies |
| Diagnostics | Single-stage studies |
| Treatment | Clinical trials  |
| Prevention | Field trials  |
| Cause | Analytical, case-control studies, cohort clinical trials |

**Descriptive methods allow to obtain objective information** about the prevalence of the diseases and risk factors among the population (to solve the *first problem* of epidemiology), to formulate hypotheses about possible etiological “impact-disease” relationships, which are checked **using analytical studies** (*second task* of epidemiology). After a sufficient amount of evidence has been accumulated in favor of the etiological nature of a particular relationship, experimental studies can be carried out, the results of which, on the one hand, are crucial for interpreting the relationship as causal, and on the other, they can verify the effectiveness of the proposed preventive and curative activities *(third and fourth tasks of epidemiology)*.

**PRACTICAL TASK**

In the district N. an adult population remain of 18400 people. It is necessary to organize and conduct a multi-purpose selective epidemiological study to identify respiratory diseases and determine their risk factors in order to develop a program to preserve and strengthen the health of the population. It is known that the estimated prevalence of skin diseases among adults is 80. (I = 80) and the settlement is located in close proximity to a large chemical factory.

For this you need:

* + to establish the degree of reliability of the planned study;
	+ determine the number of population to be included in the selected statistical aggregate;
	+ determine the best methods of epidemiological research to achieve this goal, depending on the task (the tasks are presented in the table);

Table 4

**Defining epidemiological research methods**

|  |  |
| --- | --- |
| **Task (study):** | **Best practice** |
| Prevalence |  |
| Frequency of occurrence of new cases (diseases, their consequences)  |  |
| Risk of occurrence |  |
| Prediction of morbidity |  |
| Diagnosis of diseases |  |
| Treatment of diseases |  |
| Prevention of morbidity |  |
| Reason |  |

– make conclusions.

**Task solution:**

**1. Baseline data and establishing the degree of reliability of the planned study:**

**N –** population is 18400 people.

**I** – estimated incidence of pulmonary disease 80.

**t –** reliability criterion is assumed to be 1.96 ≈ 2.

**Δ** – The maximum allowable error is determined by no more than 25% of the value of the indicator (I). Therefore, **Δ** will be 25% of 80.0 Ie: **Δ** = (25x80.0) / 100 = 20.0, **Δ2** = 400.0

**2. Determining the number of population to be included in a sample of the statistical population for the study of incidence:**

With a known population size, the sample size is determined by the formula 2:

$$n=\frac{I×q×t^{2}×N}{\left⟨N×Δ^{2}\right⟩+\left⟨I×q×t^{2}\right⟩}$$

Denote:

**n** – is the desired sample size;

**N** – is the population size;

**t** – reliability criterion (equal to 1.96 ≈ 2)

**I** – estimated frequency of diseases

**q = (R- I)** where, **R** is the used dimension of the indicator **I**

***Δ*** – selected maximum permissible error of the indicator. 25% of the value of the indicator (**I**). ***Δ*** *= 20.0 ‰*

*n = (80.0x (1000-80.0) x2*2*x18400) / (18400 400.0) + (80.0x (1000-80.0) 2*2*) =*

*= 707 people.*

3. Determine the best methods of epidemiological research to achieve this goal, depending on the task.

Table 8

**Optimal research methods**

**in relation to various issues of medicine and health**

|  |  |
| --- | --- |
| **Question** | **Research method** |
| Prevalence | Descriptive, one-step research |
| Frequency of occurrence of new cases (diseases, their consequences) | Analytical, cohort studies |
| Risk of occurrence | Analytical, cohort, case-control studies |
| Prediction of morbidity | Cohort studies |
| Diagnosis of diseases | Single-stage studies |
| Treatment of diseases | Clinical trials |
| Prevention of morbidity | Field trials  |
| Reason | Analytical, case-control studies, cohort, clinical trials |

**Conclusion:**

1. In order to obtain sample data corresponding to the required confidence, 707 people should be examined from 18400 adults.

2. Optimal methods of epidemiological research for solving research problems are presented in the table.

**TEST TASKS**

|  |  |
| --- | --- |
| 1. | Epidemiology is not only medical science. This is the main science of the field of research and practice called public health. Give the correct definition of epidemiology: |
|  | \*А | Science that studies the distribution and determinants of health-related conditions or events in a particular population for managing and controlling health problems. |
|  | В | Science that studies patterns in the health of the population |
|  | С | Science that studies the prevalence of diseases, disabilities and the factors that influence them |
|  | D | Science, studying the processes of population reproduction |
|  | Е | Science, studying the causes of violations in the state of health Science, studying the causes of violations in the health status of individual populations |
| 2. | The first task of epidemiological research is the study of any phenomenon or state of public health, which descriptive epidemiology solves. Without a qualitative description of the problem of public health, it is impossible to perform subsequent tasks of epidemiological research. What is the main task of descriptive epidemiology: |
|  | А | To establish the causes of diseases and other pathological conditions among the population. |
|  | В | To develop effective primary prevention methods using knowledge of the causes of diseases |
|  | С | To develop effective primary prevention methods using knowledge of the causes of diseases  |
|  | D | To study the clinical features of public health |
|  | \* Е | To study the frequency and distribution of diseases in a particular area, at a certain time, among different population groups, as well as risk factors |
| 3. | To solve the problems facing epidemiology, it must have special research methods. What are the epidemiological methods, depending on the purpose of the study: |
|  | А | Controlled |
|  | В | Empirical |
|  | С | Experimental |
|  | \* D | Empirical and Experimental |
|  | Е | Randomized |
| 4. | Epidemiological methods are the methods of studying the patterns of the spread of diseases and other conditions among the population, based on the use of statistical indicators. From the point of view of the duration of the observation of the state of health of the studied contingent which methods are distinguished: |
|  | А | Experimental  |
|  | В | Longitudinal  |
|  | С | One-time and cohort |
|  | \*D | One-time and longitudinal |
|  | Е | Single-stage |
| 5. | The nature of the intervention epidemiological methods are divided into empirical or observational and experimental. What is empirical research? |
|  | А | Long-term, dynamic or continuous monitoring of a specific population selected for research |
|  | В | Studies conducted on a group of volunteers with constant correction of intervention methods  |
|  | С | Studies in which the researcher purposefully and consciously controls the main parameters that are the subject of study, and also distributes the objects of research to certain groups |
|  | D | Study to identify the incidence among a small proportion of the population |
|  | \* Е | Studies without intentional intervention in the natural course and development of the disease  |
| 6. | Analytical epidemiological studies are carried out using a set of original methodological approaches based on the use of special indicators and including special schemes for collecting and processing information. What is the main purpose of analytical research methods: |
|  | \* А | Establishing causal relationships between the occurrence of the disease and various risk factors  |
|  | В | Intended to, to study the incidence in a relatively small, part of the population  |
|  | С | Obtaining information about the natural course of disease in the population |
|  | D | Study of the effectiveness of preventive and therapeutic interventions |
|  | Е | The study of patterns in the health of the population and the development of effective measures of treatment and prevention |
| 7. | The “case series” description method is the most common way to describe the clinical picture of a disease. It is quite informative and convenient for this task, but has serious limitations. What is the study of the "description of a series of cases"? |
|  | А | A study of the state of health for a certain period of time  |
|  | \* В | A study that usually includes descriptive statistics of a group of diseases  |
|  | С | Long-term, dynamic or continuous monitoring of a specific population selected for research |
|  | D | Studies conducted on a group of volunteers with constant correction of intervention methods |
|  | Е | Studies without intentional intervention in the natural course and development of the disease |
| 8. | An example of what type of research is the Framingham study, where participants were examined at certain periods of time for 30 years to determine the causes of diseases of the cardiovascular system? |
|  | А | “Case-control” |
|  | \* В | Cohort  |
|  | С | Experimental  |
|  | D | Single-stage  |
|  | Е | Sociological |
| 9. | When a routine inspection of the population of one of the district centers in 2017 was conducted, it was found that 23% of those examined had an elevated level of blood pressure. What type of epidemiological research is this study related to? |
|  | А | “Case-control” |
|  | В | Cohort  |
|  | С | Experimental  |
|  | D | Retrospective |
|  | \* Е | Single-stage |
| 10. | The reliability of the results obtained during the clinical trials is influenced by the knowledge of the participants in the experiment, which of the patients is receiving what kind of treatment. What method (method) of patient distribution in groups will increase the reliability of the results? |
|  | А | Cohort  |
|  | В | Experimental  |
|  | С | Nesting |
|  | **\***D | Randomization |
|  | Е | Single-stage  |
| 11. | The study examined the relationship between cases of acute leukemia and exposure to radioactive radiation. The following method was used: the clinic registered 75 patients with acute leukemia, determined the exposure of these patients to radioactive radiation. Simultaneously, a medical examination of 100 patients who complained of other malignant blood diseases was performed. What type of study is this? |
|  | \* А | “Case-control” |
|  | В | Cohort  |
|  | С | Experimental  |
|  | D | Non-epidemiological |
|  | Е | Single-stage |
| 12. | The study involved 79 cancer patients of the IV clinical group. All patients received new treatment. According to the results of the study, diagrams of survival of patients during treatment with a new drug for two years have been compiled. Classify this study: |
|  | А | “Case-control” |
|  | В | Cohort  |
|  | С | Descriptive |
|  | \* D | Experimental |
|  | Е | Single-stage |
| 13. | The objects of study were patients with a confirmed diagnosis of diabetes and the same number of people with similar characteristics, but not suffering from this disease. All participants were interviewed for the presence of diabetes patients in the pedigree. Classify the study: |
|  | \* А | “Case-control” |
|  | В | Cohort  |
|  | С | Experimental  |
|  | D | Prospective |
|  | Е | Single-stage |
| 14. | When analyzing the statistical information on the health status of the population of three medical sites, it was found that the prevalence of nonspecific lung diseases in men is higher than in women. Which of the epidemiological methods was used? |
|  | А | Analytical |
|  | В | “Case-control” |
|  | С | Cohort  |
|  | \* D | Descriptive |
|  | Е | Experimental |
| 15. | Sources of information about cancer cases are data from a cancer registry or cause of death. To what type of epidemiological methods can this research be attributed? |
|  | А | “Case-control” |
|  | В | Descriptive  |
|  | С | Experimental  |
|  | D | Prospective |
|  | \* Е | Retrospective |
| 16. | The purpose of the research is to study the effect of working conditions on the health status of miners. The objects of the study were several hundred miners who work in coal mines, and the same number of employees. The study compared the mortality rates and the prevalence of diseases in both groups. To what type of epidemiological methods can this research be attributed? |
|  | \*А | Analytical |
|  | В | Descriptive  |
|  | С | Experimental  |
|  | D | Non-epidemiological |
|  | Е | Single-stage |
| 17. | The purpose of the research conducted over 10 years was to study the risk factors for coronary heart disease of the male population living in different regions of Ukraine. What method of epidemiological research was used in this work? |
|  | \*А | Cohort  |
|  | В | Descriptive |
|  | С | Experimental |
|  | D | Retrospective |
|  | Е | Single-stage |
| 18. | Epidemiological methods are divided into empirical or observational and experimental. Which of the above is typical for experimental research methods: |
|  | А | Analytical epidemiological studies to establish causal links between diseases and various risk factors |
|  | В | Long, dynamic monitoring of the health of a particular contingent |
|  | \*С | Studies in which the researcher purposefully and consciously controls the basic parameters that are the subject of study |
|  | D | Studies conducted on a group of volunteers with constant correction of intervention methods  |
|  | E | The study without the intentional intervention of the researcher in the natural course and development of the disease. He observes and records the necessary information in accordance with the research program. |
| 19. | According to the duration of observation, epidemiological studies are divided into single-step (transverse) and long-term (longitudinal). What type of epidemiological research a population census is: |
|  | А | Cohort |
|  | В | Empirical  |
|  | С | Experimental  |
|  | \* D | Single-stage |
|  | E | Sociological |
| 20. | Longitudinal (longitudinal) studies are divided into prospective and retrospective. Which of the above methods of epidemiological studies was used in the study in 2010. the incidence of myocardial infarction in the period 2005–2009 |
|  | А | Analytical |
|  | В | Descriptive  |
|  | С | Experimental  |
|  | D | Prospective |
|  | \* E | Retrospective |
| 21. | For a certain group of the population (without ischemic heart disease), 5-year follow-up was established to identify new cases of this disease under the influence of endo- and exogenous factors. What type of epidemiological study was used in this case: |
|  | А | Descriptive  |
|  | В | Experimental  |
|  | \*С | Prospective |
|  | D | Retrospective |
|  | E | Single-stage |
| 22. | To identify the factors contributing to the occurrence of myocardial infarction, 2 groups of patients were taken. The first group – patients with myocardial infarction, the second – persons without this disease, which according to other main features (gender, age, etc.) corresponded to the group of patients. What method of epidemiological research was used in this case: |
|  | А | Analytical |
|  | \* В | “Case-control” |
|  | С | Prospective |
|  | D | Single-stage |
|  | E | Retrospective |

**CONTROL QUESTIONS**

1. What is epidemiology.

2. List the tasks that the epidemiology of non-communicable diseases solves.

3. What are the essential features that distinguish the epidemiology of infectious diseases from the epidemiology of non-communicable diseases?

4. What is the design of epidemiological research, its types?

5. Describe a complete epidemiological study. Inclusion and exclusion criteria?

6. Give the characteristic and features of selective epidemiological research?

7. What is randomization? Its main purpose.

8. What is the peculiarity of “blinding” epidemiological studies.

5. What is empirical epidemiological research, what methods do they include?

6. What epidemiological studies are called experimental and their main methods?

7. Describe descriptive epidemiological studies.

8. What tasks does analytical epidemiology solve?

9. What is the difference between case-control epidemiological studies and cohort studies?

10. What epidemiological methods do you know depending on the duration of the study?

11. Describe controlled and uncontrolled studies?

12. What is a cohort? Describe the classic scheme of cohort epidemiological studies.

13. Describe the classical case-control epidemiological survey.

14. What tasks can solve experimental research?

15. Describe the classical scheme of controlled experimental studies.

16. What type of clinical research is today considered the “gold standard”?

17. What is an environmental epidemiological study?

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*Educational publication*

**DESIGN OF EPIDEMIOLOGICAL STUDIES**

Methodical developments for teachers
to conduct a practical lesson on the course:

***“Social medicine, public health (biostatistics)”***

for students in the specialty:

222 “Medicine”, 228 “Pediatrics, 221 “Dentistry”.

|  |  |
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