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INTRODUCTION TO
RESEARCH METHODOLOGY



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Introduction to research methodology

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1. THE BASICS OF GENERAL RESEARCH METHODOLOGY (K. LAMPEK, ZS. HORVÁTHNÉ KÍVÉS)

1.1. INTRODUCTION

Today's societies are often called information societies since information and knowledge as the bases for technological development have become values in their own right. Today it is not difficult to find information in connection with any unknown concept, phenomenon or process any more. It is a far greater challenge to select scientifically well-grounded, 'valid', knowledge from an endless and confusing stream of information. This is even further complicated by knowledge changing ever faster with the development of science; with a bit of exaggeration it may be said that today's truth may be questioned tomorrow.

In order to to acquire and maintain competitive knowledge in the labour market scientifically based knowledge is more and more important . And it is exactly like that in health care and among professionals in health sciences, where in order to implement empirically based care it is indispensable for employers to be knowledgeable concerning new scientific results in their fields and to be able to interpret and apply them appropriately. Being able to carry out methodologically sound research producing reliable results either individually or as a team may also be of importance.

But how is new scientific knowledge born, how does it evolve, what are its conditions, what methods is it achievable by, how do scientific questions become proven realisations and then parts of practice? In this chapter the basics of research methodology and the process of scientific research are presented. For better comprehension examples from health science are used to illustrate the theoretical bases. This can be carried out as in the last few decades thousands of studies have been published in this field, which is also attested by numerous scientific databases. (Betlehem, 2009)

The presentation of the research process in this chapter ends by selecting the research methods as the forthcoming stages (data analysis, publication of scientific results) are dealt with in detail in consecutive chapters.

1.2. SOURCES OF KNOWLEDGE

Humans are rational creatures; their actions are more or less knowingly structured. However, everyday decisions do not always need explanations, opinions do not necessarily require justifications and the sources of knowledge are rarely documented. Information is acquired in two basic ways in everyday life: one is direct experience with subjective impressions while the other one happens when knowledge from others is accepted, which means that this kind of obtaining knowledge is based on consensus. The first method is called empirical reality, while the latter is called consensual reality. (Babbie, 2008)

Nevertheless, rationality, logical argument and the use of well-grounded claims are indispensable in study, work and especially in scientific activities. In scientific cognition the goal is finding the objective and proven knowledge, which is often a rather difficult task. The solution is provided by scientific research methods as from a scientific perspective a statement is only acceptable if it is regarded both logically and empirically proven.

1.3. THE CONCEPT, IMPORTANCE AND AREAS OF APPLICATION OF SCIENTIFIC RESEARCH

Scientific research has been defined by many, with some shocking definitions given. According to anthropologist Zora Neale Hurston “Research is formalized curiosity. It is poking and prying with a purpose.” According to Albert Szent-Györgyi’s famous saying “Research is to see what everybody else has seen, and to think what nobody else has thought.” Within the research methodology literature one can, of course, find more conventional as well as formal definitions. A widely accepted definition reads: In scientific research, contrary to the possibilities of acquiring everyday knowledge previously mentioned, the researcher collects data in a planned and regulated manner after identifying the research problem and raising the research question, processes and analyses the data and makes them available to others complying with the requirements of scientific publication regulating content and form. (Héra, Ligeti 2005)

Babbie (2008) points out that the two pillars of science are logic, i.e. rationality, and observation. He regards both of these as fundamentally important and believes they can be achieved by creating theories, research methodology and statistical analyses.

According to Eco (2002) research is concerned with a recognisable object – not necessarily in the physical sense of the word – which is defined in a way as to allow others to recognise it too. The essence of science is to produce new results not published by anybody else before,

and this result also has to be beneficial to others. Finally, scientific research has to provide elements for proving or disproving a particular hypothesis not only in connection with the research done but also for continuing the ongoing research.

Wartofsky (1977) considers science to be an organized or systematic aggregate of knowledge which contains general laws or principles. Concerning those pursuing science he notes that one can speak about scientific results if scientists speaking a common language show consensus relating to the subject. He is also the first to point out that science distances itself more and more from knowledge applicable in everyday life and scientists do their work isolated, often even from their human relationships.

Science and scientific thinking are an indispensable part of development. At the same time, however, it is a fact that the result of a given scientific research is not a solution to a given problem by itself but it helps understand and become familiar with the phenomenon investigated, and thus accept or reject the facts known so far. Consequently, the goal of research is to update and enhance knowledge for well-defined purposes.

Surely, it will not be surprising to anyone to say that to experts information acquired in scientific research is the most accepted and most reliable. What was said above may suggest that only scientists can do and actually do scientific research. However, research may be done for a variety of purposes, including writing theses and dissertations, for acquiring a scientific degree, etc. And that is why many may need to know the methodology of scientific research, so that the results of their research will lead to well-founded conclusions. In addition, the knowledge of research methodology can be important to those too who do not participate in research as in order to read a scientific article or to accept a newly published scientific result critically thinking they need to know the right methodology of research.

As a matter of fact, this task is still to be solved. While health science produces newer and newer theories and research results, very little is known about how they become part of everyday life and work and in whatever decision-making process they become, and how well-justified their selection is. Additionally, in fact, it was this problem that led to one of the main areas of research in health science these days: the issue of evidence-based practice (EBP). Dicenso et al. (2004), for example, pointed out that evidence-based nursing was a clinical decision-making process, during which it is important to base decisions on the best evidence and research results available taking individual patients' characteristics, circumstances and preferences into account.

Health science research in the last decades has been aimed at several areas of research that can be considered new. Of these the following are worth highlighting due to their great significance:

- researches on increased life expectancy and the quality of life;
- investigations exploring the possibilities of prevention and health promotion;
- studies on accessing and the effectiveness of health care;
- epidemiological researches for handling and solving the problems of public health;
- surveys on patient satisfaction in health care;
- health economics researches, the investigation of cost-effectiveness and quality health care, etc.

1.3.1. Difficulties of scientific research

When carrying out scientific research one may encounter numerous difficulties.

First of all, a significant part of research – often in health science too – involve the participation of people. And their presence may be fundamentally influenced by a number of factors, which may have a distorting effect, and these can be barely or absolutely unplanned. Such factors are, for example their current mood, the experiences they have just gone through, their problems, etc.

Compared to other studies, research involving people always face the insoluble problem of forming a homogeneous group of participants. Apart from complying with the main criteria for selection for the research, participants may have a wide variety of different characteristics and features, which may affect the research results.

In the case of scientific research involving people – contrary to most scientific researches – tests are difficult to repeat or reproduced and not only because of the research costs but also as the participants may be in a partially or totally different life situation. Thus, changes often take place for reasons which may be difficult or impossible to measure and are other than those examined.

In studies involving a representative sample results can be distorted if the participants do not actually represent the population from which they have been selected. For example, in the case of volunteering participants, the group examined may represent a population that is more sensitive towards the given issue than the average population. It could also happen that those conducting the study select the participants wrongly, as they subconsciously apply criteria which affect representativeness in a negative way.

Another pitfall is if different people assess the groups investigated, as they may categorize various factors differently, which may change the results. Different appliances may be used for measuring given parameters resulting in differences between the particular groups.

Scientific research also raises a number of ethical issues.

The protection of the personal information of people participating in scientific research has to be guaranteed at all times. This often causes problems in the implementation of research as it may make the exact identification of the population examined impossible. For example in the case of research among the Roma population in Hungary, it is not known who or how many belong to those groups since keeping records of people's ethnicity is illegal in Hungary.

Guaranteeing that all participants are volunteers and that they remain anonymous is a serious requirement in every research project. Furthermore, participants' rights and safety must be guaranteed; they must not be violated.

Another important ethical requirement is that researches carried out among people are subject to permission by an ethical committee. Regarding researches in health science the best-known organisations are the Scientific and Research Ethical Committee of the Health Science Council and the [Regional Institutional Scientific and Research Ethical Committees](#).

Finally, it should also be stressed that publishing the results of scientific research is also an ethical obligation. Another basic rule concerning publication is the prohibition of plagiarism, i.e. the presentation of scientific results published earlier by others as one's own. Therefore, in scientific publications the name(s) of the original authors have to be clearly indicated according to the rules of the given referencing style.

1.4. THE PROCESS OF SCIENTIFIC RESEARCH

In scientific research, following the determination of the research problem and the research question, scientists systematically collect, process and analyse data and then make them available to others according to the requirements for the content and form of scientific publications. The stages of scientific research are illustrated in figure 1.

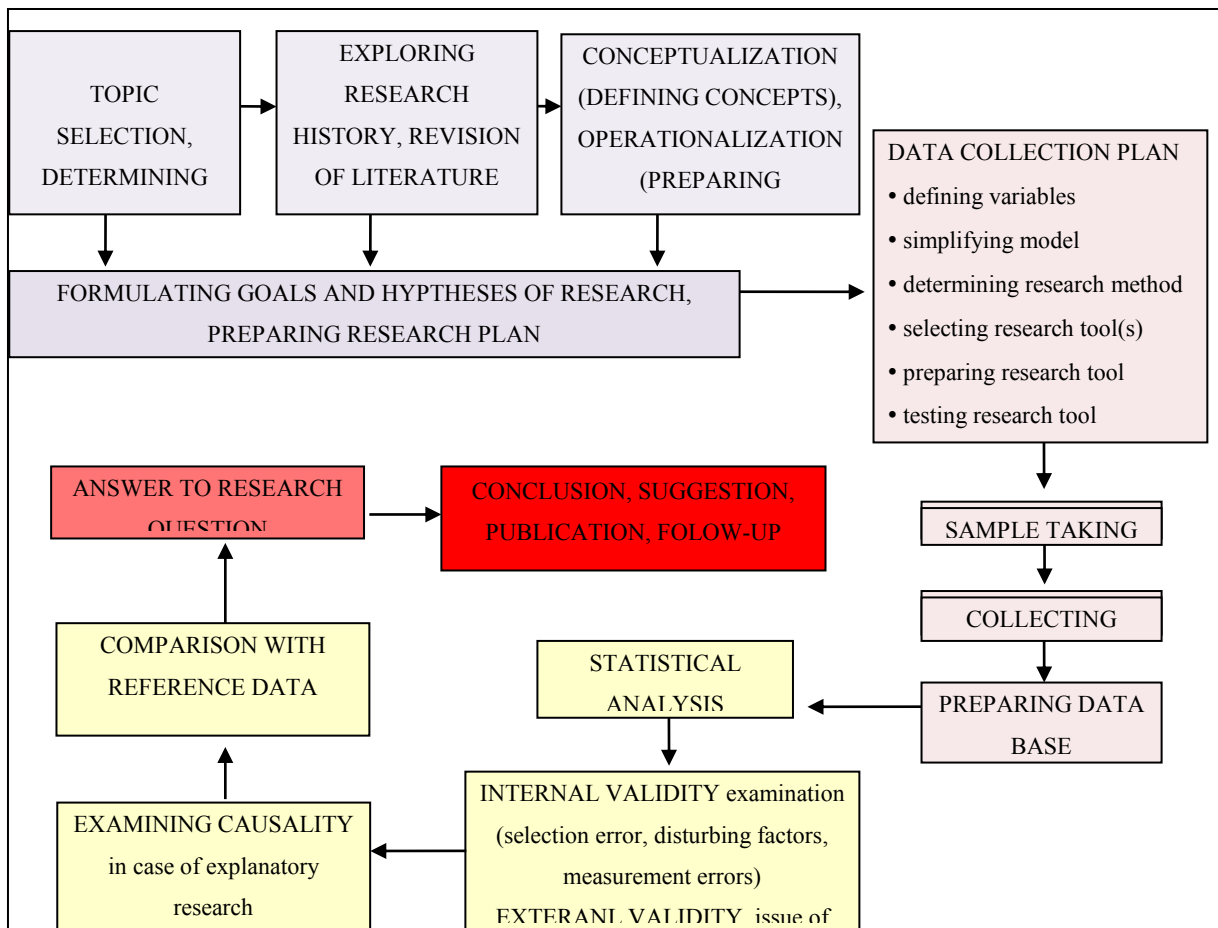


Figure 1: The process of scientific research

1.4.1. TOPIC SELECTION, DETERMINING RESEARCH PROBLEM

The first and most fundamental question to be answered in the research process is what topic to choose as the subject of research.

While selecting a topic it is advisable to consider some important aspects:

- the selected topic should suit the researcher's interests, education and previous researches;
- availability of literature in the chosen field, perhaps contact with a researcher knowledgeable about the topic, who can give professional advice during planning as well as implementing the research project;
- concerning time and costs, research in the chosen topic should be easy to plan;
- the boundaries of the selected topic (size of sample, number of observations, required volume) should be well-defined, as a topic that is too broad leads to problems of solution the same way as one that is too narrow;

- if the supervisor for the research topic can be chosen too, it is important to ask someone knowledgeable and experienced in the given field. The aspect of willingness to cooperate and a friendly relationship between the researchers should not be neglected either, since numerous difficulties may arise during a research project, and good personal relations can greatly help to overcome them.

Having selected a topic, it has to be determined what research problem or question the researcher seeks an answer to. A researcher's interest can be formed by a wide range of issues and questions, such as:

- problems to be solved in everyday practice;
- reconsidering the theoretical principles of a given discipline, examining their validity and reliability;
- looking for answers to questions unanswered by the literature;
- an urge to scientifically prove personal intuitions, observations and beliefs.

An indispensable requirement of determining the research problem is the accurate identification of the questions to be answered and the clarification of the research goals. One of the most common mistakes is trying to answer a wide a range of research problems because the researcher fails to determine the boundaries of the research in advance. In fact, well-defined research questions also even provide the answers more or less, since a precisely identified problem also determines the goals to be reached as well as the necessary sources of data.

The topic selection and the identification of the problems and questions basically determine the type of research to be done. According to a classification of researches there is basic and applied research and within applied research we differentiate between evaluation, action and orientation research.

The objective of basic research is to generate fundamental and theoretical knowledge related to nature or society. In such researches data gathering normally aims at answering theoretical questions and researchers carry out empirical observations to that end. Applied research concentrates on answering practical questions in order to provide useful solutions which are relatively directly applicable.

Within applied research, evaluation research is meant to determine the value or quality of an object or process examined. According to their objectives these may take the forms of:

- formative evaluation, which examines changes (improvement) in a process or in the condition of an object, or
- summative evaluation, which provides a comprehensive assessment of the current status of a process or object, and the assessment is mostly followed by a decision on continuing or discontinuing the given process or programme.

Another type of applied research is action research, which concentrates on solving practical problems occurring in a narrower field. Here the emphasis is not on producing new knowledge but on intervention.

Finally, the third type of applied research is orientation research, which formulates a critical theory or perspective and mostly focuses on some difference, inequality or discrimination. (Babbie, 2008)

According to research problems one can speak about exploratory, comparative, diachronic and explanatory researches. (Table 1)

Table 1: Research types

Research type	Main questions	Example
Exploratory research	What happened ...?	What are the typical infant mortality data in European societies?
	What are the main characteristics ...?	
	Under what conditions does it occur ...?	
Comparative research	Does it occur elsewhere ...? How...?	To what extent do infant mortality data differ in European societies?
	Under what conditions does it occur ...?	
Diachronic research	How did it happen earlier ...?	How has the extent of infant mortality changed in European societies over the last 100 years?
	What were the characteristics earlier ...?	
	How often does it occur ...?	
Explanatory research	What causes it?	What are the causes of infant mortality in European societies?
	How is it related ...?	
	What are its effects ...?	
	What are the consequences ...?	

Formulating a research problem is not an easy task; it usually needs a lot of deliberation individually and/or in a team. There are no general rules on how it is done but some important requirements can be listed. The research topic should be about a characteristic professional problem and it must fit in with the given discipline, but multidisciplinary, being related to other disciplines, is a common element of researches too. Researchability, the feasibility of empirical investigations and the utility and applicability of the expected results are also important aspects of research problems. The feasibility of researches is subject to numerous conditions, which are only simply listed below, but in the case of particular researches they all deserve thorough consideration:

- time available for the research and its schedule,
- availability of people involved in the research and their willingness to participate,
- availability of research tools,
- financial resources,
- researcher's experience and commitment
- ethical considerations.

1.4.2. Exploring research history, the revision of literature and other sources

One of the basic requirements for scientific researches is the familiarity with the literature related to the research topic. It is necessary for several reasons. The researcher must be aware of the main theoretical and empirical results of available knowledge, the main research teams, the debates about the topic, the different opinions, the methodological tools applied in the research of the topic, the limitations and difficulties of researches in the field, etc. Reviewing the literature is of utmost importance; it is dealt with in detail in the third chapter of this book.

1.4.3. Creating a conceptual framework for research – conceptualization and operationalization

In the background of research there are often problems to be solved from practical professional life. That said, it still needs to be clearly seen that empirical research is always theoretically founded. Thus, at the beginning of the research it is important to create a theoretical, conceptual framework in which the research problems, the related concepts, the variables to be used and the hypotheses to be answered are to be interpreted.

An important starting point for scientific researches is the fact that on the basis of the available knowledge a particular problem cannot be answered. That, however, does not mean that the research can be started or done without a theoretical foundation. Researches lacking a theoretical frame are hard to integrate into the scientific knowledge accumulated thus far. In such cases there are no principles, no points of reference or links. *Theories* supporting the treatment of a research problem *serve as starting points*, provide foundations for the researchers' perspectives and approaches and direct the research process. Knowledge already available determines the research questions and helps develop the tools, analyses and interpretations used in the research. (Majoros, 2004)

What are the functions of theories? The simplest answer is that theories provide rational and methodical explanations in a generalizing way – often also creating models – about the phenomena studied and their reasons and interrelatedness. Theories consist of statements in which every statement follows from another and provides logical explanations for the phenomena. Scientific theories can be grouped in several ways the two most common of which are presented below:

According to the *generalizing, comprehensive aspect* of theories there are:

- grand/macro theories, which approach phenomena in their entirety conceptually and comprehensively and are difficult or impossible to test empirically,
- middle range theories/meta-theories, which apart from presenting well-defined phenomena in detail also interpret their occurrences, reasons and consequences in an empirically-grounded way,
- laws, which are theories describing the regular operations of the given phenomena. In natural science laws are function-like (a certain phenomenon always occurs under given conditions), in social sciences they are probability-like (a certain phenomenon occurs under given conditions with a predictable probability).

According to their nature their theories can be:

- descriptive theories, which present the characteristics and dimensions of a given phenomenon or groups of phenomena (main questions: what is it, what is it like?).
- explanatory theories, besides the characteristics of the phenomena studied they are complemented by the analyses of internal and external relationships, thus providing explanations for the origins/existence of the phenomena (main questions: what is happening, how is it happening, why is it happening?).

- predictive theories, which examine the causes of phenomena and the consequences related to their changes (main question: what are the consequences?).

In health science researches one mostly encounters meta-theories or laws describing phenomena and mainly descriptive or explanatory theories are applicable but predictive theories are also more and more often becoming the theoretical framework for researches.

Besides creating theoretical, conceptual frameworks, another important element of researches is *conceptualization*, the *clear definition of conceptual frameworks* used in the research. This is necessary as even well-known notions may often hold different meanings to different people involved in a research. In addition, later it will also be possible to associate possibilities for measurement with the phenomena studied. For that purpose the concept to be examined is broken down into components, i.e. dimensions, thus determining and examining how the dimensions are created. These will be the indicators of the research. The purpose of the indicators is to be able to measure the changes of the phenomenon examined, which may provide a starting point for assessing the changes in a later impact assessment.

In every research the process of conceptualization is followed by *operationalization*, i.e. the process of making something measurable. Operationalization involves procedures and processes that allow the empirical study and *measurement of the variables in the research* (characteristics, concepts). Measurement is a process in which numbers, so-called data, are associated with the selected characteristics of the phenomena or processes examined according to given rules. Setting the accuracy suitable for the research objectives, the range of the measurement, the values of the variables and the level of measurement require the researcher's decision. Since the modes of measurement may need to be revised all through the research, operationalization may have to be done by the researcher at any stage (even during analysis).

1.4.4. Formulating the goals and the hypotheses of research

A hypothesis is a statement, an assumption about the expected results of the research, which has to be either proved or disproved. A hypothesis is logically deducible on the basis of available theoretical knowledge, which needs to be confirmed by data from empirical research. In the hypothesis of a research a characteristic causal relationship related to the object of the research can be stated. That is the reason why the hypothesis is the guideline of the research, which determines what is worth investigating. Researchers always need to be very careful formulating their hypotheses, which have to be fundamentally based on earlier knowledge concerning the topic. Thus, thorough familiarization with the relevant literature prior to the research is essential. It is important that a good hypothesis should point towards new insights and approaches and it should transcend or question earlier knowledge. Hypotheses show the direction of data collection on the basis of which factual data must be gathered and their relationships explored. Preferably several hypotheses are required for a single scientific problem and they always need verification because that is the only way to establish the relationship between theory and experience. (Lampe, Kivés, 2012)

The example below illustrates the necessary components of a hypothesis.

Hypothesis: infant mortality is more common in the case of mothers aged less than 18 years.

- determining the dependent and independent variables (age – infant mortality),
- form of the relationship of the dependent and independent variables,
- the direction of the change caused by the independent variable (infant mortality more common in the case of mothers aged less than 18 years),
- naming the population involved in the investigation (the geographical characteristics or any other features of the sample may be determined in the hypothesis, e.g. mothers giving birth aged less than 18 years),

The requirements related to hypotheses are summarized below:

- appropriateness – it must relate to the problem examined, it must contain the characteristics of some phenomenon;
- conceptual clarity and unambiguousness– the precise definition of the related concepts, i.e. conceptualization, is already necessary at this stage;
- simple and concise formulation;
- it must be based on available knowledge, it must be factual and theoretically well-founded;
- empirical testability;

- connection to available technical devices – it is worth formulating hypotheses for which the necessary tools are available but may lead to the recognition of new research tools;
- the relationship between the variables must be both logically and theoretically well-grounded;
- it must not be trivial; it must focus on a question really needing an answer.

Hypotheses are articulated in two forms. Concerning the research assumptions a so-called null hypothesis and a research or alternative hypothesis are determined. An alternative hypothesis may have two further versions, such as directional and non-directional alternative hypotheses. A null hypothesis mostly states the absence of a difference or change, while an alternative one states the opposite, the verification of which is expected from the research. Continuing with the previous example, a 1+2 hypothesis will look like this:

- Null hypothesis: There is no connection between participating in breast cancer screening and school education.
- Non-directional hypothesis: There is a connection between school education and participating in breast cancer screening.
- Directional hypothesis: Having higher education qualifications results in higher attendance at breast cancer screening.

1.4.5. Preparing a research plan

After formulating the research problem it is worth preparing the plan of the implementation of the investigation, which guides the researcher through the whole process. This already takes place during the first stage of the research. Why is this necessary? The answer follows on from above: the mental modelling of the process may shed light on the difficulties of realization and/or any insoluble problems. Nevertheless, it is even more important that a process based on a research plan which is coherent and characteristic of the entire research has to be created. During planning it is worth linking every phase to the earlier ones and inspecting their succession. Thus, one can avoid the mistake of having to significantly modify completed tasks or, in an extreme case, having to start the whole research over again. You must not be afraid of this task! Designing a research project is not a simple thing but it forces the researcher to determine the stages of their research work professionally.

The main elements of a research plan are the following:

- preparing a concise, well-structured summary on the basis of a review of the relevant international and domestic literature. It is advisable that every literature review should involve the presentation of the goal, hypotheses, research materials, methodology applied and results of the research.
- in the presentation of the investigation planned it is necessary to include the following:
 - problem definition
 - the goal of the study
 - the formulation of the hypotheses
 - type of the research
 - research material
 - selection of the sample (target group, criteria, method of sampling)
 - determining sample size (case group, control group)
 - the place and time of the investigation
 - the methods of data collection (primary, secondary)
 - the presentation of the variables (dependent and independent)
 - the method of statistical data analysis
 - the expected results

1.4.6. Planning data collection

1.4.6.1. Measurement methods and data types

The tasks of measurement were already mentioned at the points of conceptualization and operationalization. Measurement means assigning numbers to information gained in the research according to some rule. The numbers characterize some feature of the persons or phenomena examined quantitatively and they are called data.

In scientific research these data are assessed and it is through them that information concerning the group or phenomena investigated is sought. Data are classified in two groups: *quantitative* and *qualitative* data. Quantitative data describe the numerical values of a measured variable (e.g. blood pressure, fever, cholesterol level, body weight) while qualitative data describe the type of observations, which are assigned numeric values, e.g. smokes (=1) and does not smoke (=2). For the description of data various, basically four types of, measurement levels are applied depending on the content of the values acquired by measurement or observation. The measurement levels affect research design, data collection

and greatly influence the research process, furthermore, statistical methods also depend on scale.

On nominal scales data acquired by questionnaires and/or interview questions are measured. The symbols or numbers only serve as identification and they allow a clear classification of phenomena or processes. Particular numbers do not express quantitative or ordinal differences; they are only used for coding categories, e.g. sex, marital status, nationality bespectacled.

The type of data measurable and ranked on an ordinal scale is obtained when respondents are asked to establish an order. The order of the numerical values assigned to the data is clear; it is obvious which is greater or smaller. However, it cannot be established how great the differences between the factors ordered precisely are, e.g. settlement types, school grades, self-assessment of health status and degree of satisfaction.

In the case of data interpreted on an interval scale the order is known and clear but the distance between any two values closest to each other is the same both numerically and in content. That means that, e.g., in the case of measuring fever the distance between 36 and 37 °C is the same as between 37 and 38 °C. However, on the scale there is no fixed starting point (point 0); its place is arbitrary or based on convention, e.g. body temperature, blood pressure, IQ.

Ratio scales are the most rigorous measurement level: besides order and the equal distance of data the ratio of their difference is measurable too. If somebody has lost 20 kg in a lifestyle programme while another person only 10 kg, it is obvious that the first person has lost exactly twice as much weight as the latter. In the case of this level of measurement the starting point (point 0) has real content, since it is exactly known what it means if someone has not lost a gram or if something does not exist at all, i.e. it is 0 kg, e.g. body weight, height, heart rate, income.

1.4.6.2. Defining variables

For the analysis and interpretation of the data acquired in the process the results need to be expressed by numbers, variables must be created. Thus the particular research elements and/or people's data are made comparable, of course, taking certain conditions into consideration.

Variables are either categorical or numeric.

Categorical variables do not express values indicating quantity or quality; they only differentiate between the particular cases of the characteristic examined. Such a variable is,

for example, sex, which only has two so-called attributes/values: 1= male; 2 = female. In the case of numeric variables the values of the variables expresses the order of the particular values, moreover, sometimes even the measurable distances between them too. An example of the first variable could be school education and for the latter income or the amount of alcohol consumed.

Numeric variables can be classified further: into discrete or continuous groups. The possible values of discrete variables are limited, e.g. the number of children per family can only be a whole number, which is rarely higher than 6-8 in Hungary. Contrary to that, age is considered a continuous variable. The borderline between discrete and continuous variables is somewhat arbitrary but in practice a variable is thought to be continuous if the number of its possible values exceeds twenty.

According to their places in examining relationships, variables used in research can either be independent or dependent. Independent variables are those which are regarded as causes in casual relationships and their changes affect the dependent variables, effect. It is important to note that the 'position' of independent and dependent variable differs from research to research. There are variables that are often independent (marital status, school education, occupation, residence, etc.) but may become dependent in the case of certain research goals, e.g. school education and Internet use. It can certainly be proven that people with higher education use the Internet more than those less educated. But the statement that as a result of more Internet use someone becomes more educated may also be true during research on e-learning.

1.4.7. Determining research method

In determining the methods of researches one has to make a decision on whether the research goal is attainable either by qualitative or quantitative methods, or perhaps by using the two together. Both methods have been used in social as well as natural sciences for a long time.

1.4.7.1. Quantitative research methods

Quantitative research methods are based on the assumption that extensive quantitative data collection with a wide range, systematic, regulated and unified measurements and numerical expression are important tools in the process of gaining information as research questions can be answered based on that. Quantitative researches tend to be deductive; researchers typically collect information on a large sample in order to verify their hypotheses, their theoretical

statements. Sample selection is an important element of quantitative research because reliable results are to be obtained only by using a sample that represents the population studied well. In this type of research the use of mathematical-statistical methods is indispensable as the large sample and the research results are published in a numerical form taking the requirements of statistical reliability tests into account. Its main research tool is the questionnaire-based survey (survey technique), beside which numerous other tools are also known, such as the structured interview and the structured observation, etc. In health science research quantitative researches are used, e.g. in satisfaction studies, need studies or the investigation of health status and the factors affecting it.

1.4.7.2. Qualitative research methods

The results of quantitative researches supported by numeric data are suitable for verifying hypotheses in many fields but they often record only information occurring on the surface and do not allow a deeper understanding of problems, processes and human behaviour. Qualitative research methods, in which research focuses on a qualitative insight into phenomena, collecting and analysing opinions, attitudes and beliefs, are meant to overcome these shortcomings. Such investigations carry out a detailed and thorough exploration of the topic examined and use a small sample, in which representativeness is not an objective. For studies carried out by the qualitative technique interactivity, the inductive approach, flexibility and reflexivity are typical. There are no concrete questions determined in advance as in survey research; only the main groups of questions are the same, since highlighting the individual characteristics is one of the main purposes here. Some typical qualitative methods include: observations, experiments, in-depth interviews, expert interviews, focus groups and case studies. Qualitative researches often deal with, for example, people's beliefs concerning illnesses, exploring doctor-patient relationship problems or motivations affecting co-operation among patients.

1.4.7.3. The 'battle' of the quantitative and qualitative research methods

In research methodology the validity and applicability of the two methods in acquiring relevant scientific knowledge is a constant issue of debates. Qualitative researchers claim that a significant part of the problems formulated as research problems cannot be quantified; they can be measured only at a normative level, which is not conducive to furthering scientific knowledge. They deny that, for example, attitudes or beliefs can be measured by scales,

which they consider engineered instruments which allow a simplification of reality but do not make it more accessible. According to many, scales in questionnaires – in spite of their being standardized – may be interpreted by research subjects in extremely different ways, while according to the researchers' assumptions the 'object' of the measurement is the same. Another weak point of the quantitative method is that the data obtained by research only have reduced information contents, and they do not reflect further important components influencing respondents' answers (e.g. mood, situation, environmental factors). In spite of all these problems, the quantitative method is widely used and numerical expression is an indispensable condition in many cases; it is the high number of cases that is a basic condition of scientificity. It can be illustrated by evidence-based practice, where the existence of a sufficient number of objective and numeric results is a requirement for evidence of the highest category of qualification.

Qualitative research methods are also often criticized mentioning their limitations and shortcomings. The problem most often mentioned is that due to the low number of cases there is no possibility for generalization. Thus, obtaining scientific results by this method is extremely limited. Another issue listed among the problems of the method is that researchers working with qualitative techniques do not comply with the criteria of objectivity, validity and reliability in their investigations. In today's health science research, however, one can see that more and more researches apply the two basic methods, combining their advantages and eliminating their drawbacks. Such studies are made, for example, in validating various scales, questionnaires and research tools and the assessment of new intervention procedures.

1.4.8. The basic concepts and forms of sampling

The basis of the issue of sampling is that in most cases the examination of the entire population is not possible. Consequently, a smaller group (sample) must be selected, and generalizations about the larger population can be made by studying that. Thus, sampling involves determining and selecting the circle of those to be observed. The *sample* means all the elements, while the *elements* are the basic units about which information is collected and serve as the basis of the analysis. These are usually people but they can also be lifeless things, e.g. tools used in healthcare, sickbeds, etc. *Population* is the theoretically determined totality of elements to be examined, i.e. persons or things that suit the previously defined selection criteria and that conclusions are to be made about. The *target population* is a narrower circle meaning all the persons or things of whom/which the actual sample is taken. While sampling

one has to ensure that the sample represents the population. **Representativeness** means that the aggregate characteristics, properties and parameters approximate the same aggregate characteristics of the population well. A sample does not need to be representative in every aspect; it suffices if it is limited to the characteristics important for the specific research, e.g. sex, age, school education and geographic location (Pakai and Kívés, 2013).

If the study of the whole population or target population is possible, one cannot talk of sampling as defined above but a **total investigation**, the results of which clearly and reliably describe the characteristics of the population examined.

Sampling procedures can be classified in two groups fundamentally: random and non-random sampling.

In **random or probability** sampling every member of the population has an equal chance of being selected. The sample thus chosen represents the population sufficiently. Consequently, the conclusions drawn can be considered well-founded. In research one should try to use probability sampling, which, however, is often difficult due to, e.g. reasons of data protection, funding, or because no list of the population to be examined is available for selection.

Sampling can be done in several ways:

- In the case of a **simple random sample** members of the sample are selected randomly from an available list of the population. The elements of the list are assigned ordinal numbers and then they are selected with the help of a random number table or a computer.
- In a **systematic random sample** every k th element of a complete list is selected. For example, if the population consists of 1000 (N) and a sample of 200 (n) elements is needed, every 5th (k) element of the list shall be selected for the sample ($k=N/n$). If the elements in a list are arranged according to some system, it is not advisable to choose this method.
- In a **stratified random sample** the population is divided into homogeneous subgroups and a sufficient number of elements is then selected from each. The strata may be created, for example, according to sex, age or place of residence. It can be used if the ratio of the particular strata is known in the population.
- In **stratified random sampling with proportionate allocation** sample is selected proportionately with the population. The elements are chosen with a systematic method from the groups created.

- By ***cluster random sampling*** not individual elements but groups are randomly chosen. It can be really useful if a complete list of the population is difficult to prepare.
- In multi-stage sampling groups are selected first, then lists are made of the members of the groups and then the sample is taken from the lists randomly. This form of examination is often used in epidemiological and multicentric studies.

Non probability samples cannot guarantee representativeness. Thus, conclusions drawn from them are limited. Individual elements have smaller or greater chances of being included in the sample.

- ***Accidental or convenience sampling*** means when one relies on subjects easily available for the research among their acquaintances or colleagues. It may be used if the researcher is actually interested in those being present at the given moment or other procedures are not feasible. It is suitable for testing questionnaires and preparing larger representative research.
- In the case of using a ***purposive or purposeful sample*** the researcher knows subjects with which qualities they need and they look for those. This method is mostly used in qualitative research.
- ***Snowball sampling*** is applicable if defining the members of the population is difficult, e.g. homeless people, migrants. The researcher collects data from some people they can find in the population examined and then he/she asks them for the contact details of acquaintances belonging to the population. The word ‘snowball’ refers to gradual growth; people contacted suggest further people. It is used for exploratory purposes primarily.
- ***Quota sampling*** is the non-random method of stratified random sampling mentioned earlier. The population is divided into subgroups (might be even proportional), from which, however, elements are not chosen randomly. It is a more reliable procedure than simple non-random sampling but it does not guarantee representativeness. (Parahoo (2006), Lehota (2001), Lázár (2009), Pakai and Kívés (2013), Babbie (2008))

1.4.8.1. Inclusion and exclusion criteria

Prior to sampling it is advisable to determine those - especially extreme - characteristics and properties that may distort results and/or affect the homogeneity of the sample. In many cases the details of the inclusion criteria also determine those excluded, but it may also happen that only a few exclusion criteria are given. Inclusion criteria often include age group, diagnosis of

illness, stadium, form of treatment, geographic distribution of subjects, etc. Exclusion criteria may be, for example, difficulties of reading and writing.

1.4.8.2. Sample size

Sample size is partly determined by professional considerations, partly by statistical methods. From the perspective of sampling it is critical *how important the obtained results* are and what *purpose* they will be used for. For the preparation of decisions with long-term consequences affecting many people, larger samples are necessary. If the *effects of the variables examined are strong* and cause significant changes, smaller samples may suffice. If the *variable examined affects the individuals in the study differently*, i.e. the more strata influencing the effect are present in the population, the larger sample is needed in order to eliminate the ‘distorting’ effect of the people present in the sample. A larger sample is required also in the case of the heterogeneity of the population and a high number of variables investigated. The *method to be used* (questionnaire: higher number of elements, observation: higher number of elements) and the *time and costs required* by the research are also decisive.

1.4.9. Primary and secondary research methods

In primary research first-hand information is gathered and analysed. The type of a research can be qualitative or quantitative. The methods of experiments, questionnaire-based surveys, observations and interviews belong primarily to this group. In secondary research the data to be processed come from other sources and they were recorded for purposes other than research. (Parahoo (2006), Lehota (2001), Lázár (2009), Pakai and Kívés (2013), Papp (2013))

1.4.9.1. Primary research methods

Although conducting experiments in health science research is often limited, it is still indispensable for evidence-based care and everyday practice. During the experiment the researcher systematically examines the causal relationships between the variables to see if an effect or result is attributable to a given treatment or not. In health science researches experiments are usually called clinical trials. This procedure is applicable for the examination of the results of certain interventions, e.g. therapeutic methods, training programmes, interventions and instruments used. An experiment may primarily focus on how a particular procedure works (*explanatory research*) or on verifying the effectiveness of an intervention

(*practical research*). There are basically two forms of experiments: true experiment and quasi-experiment researches.

In **true experiment** research intervention, control and *random sampling (controlled random trial – CRT)* are present simultaneously. Without *intervention* there is no experiment: the researcher must do something during the experiment to create an effect. It is by using a control group that it is demonstrable that a given variable is responsible for a result. Control is especially important in the case of variables that can cause the result both by itself or with other variables together. For example, if a researcher wishes to test the effectiveness of a given bandaging material, he/she cannot be absolutely sure of the effectiveness of the procedure applied because the healing of a wound is affected by other variables besides the bandaging material, e.g. protein input, other local treatments and medication. Furthermore, it can happen that the condition of the wound may improve ‘in time’ anyway. In this case the bandaging material to be tested will be applied for the treatment group, while for the control group the traditional procedure will be used.

A **control group can be formed** in several ways. In *intersubject or parallel group design (parallel groups)* two (treated/control) or perhaps more groups can be compared. The number of the groups depends on the goal of the experiment. In *intrasubject or crossover design* the same subjects receive one treatment after the other. It is applicable mostly for chronic diseases, where recovery is not expected from the treatment only the alleviation of the symptoms, an improvement in the condition. It is advisable to apply it for short treatments. A problem in this arrangement may be that the effect of the first treatment continues during the period of the second one. That is why a certain period must be skipped between the two interventions. In planning an *individual case* only one or a few participants are involved in the research at one time. This arrangement is useful in cases when little is known about the effectiveness of the intervention. The greatest limiting factor here is the fact that the observations cannot be generalized for the population. In the **Solomon four-group design** four groups are made: two treatment groups, in which the intervention takes place, one of which undergoes pre- and post-tests, while the other one is only post tested, and two control groups, where again one of the two undergoes pre- and post-tests, while the other one is only post-tested. In this design distorting external variables are easier to control. In *factorial design* the effects of two or more independent variables are tested in the same research for one or more dependent variables. Here the term ‘factor’ refers to variables. It is suitable for examining the interactions between variables, the combinations of interventions.

Apart from the methods described above there are further possibilities for **random sampling** in experiments. In the **matched-pairs design** the subjects are placed in the treatment and control groups according to their main characteristics. For example, if we want to study women with low education diagnosed with cervical cancer, one in each pair of subjects fulfilling the criteria is put in the treatment group and the other in the control group. The method is applicable if the researcher knows the control variables. Instead of dividing the individuals into groups one can choose **clusters** (*cluster randomized trial*) (e.g. hospitals or care homes) instead of individuals. Thus, every subject of a given cluster is put either in the treatment or the control group. By the **randomized blocks design** the undesirable effect on the result variable can be controlled. The individual blocks, i.e. strata, are designed according to that effect. For example, three treatments are compared in an experiment (the element number in the sample is 5 pers.) and all the measurements need to be done in one day, the values of the target variable may differ according to the time of day, furthermore the procedure is time consuming, the measurements last from morning till evening. In such a case five blocks can be created (early morning, morning, noon, afternoon, evening) with three measurements per block (one of each treatment), randomizing the treatments within the blocks.

For several reasons - ethical, practical, organizational - it may happen that true experiment research related to health care cannot be done. An alternative solution to that is provided by **quasi-experiment researches**, which *do involve intervention, but either the control group or random sampling is missing*.. Here the external variables cannot be controlled appropriately. Thus, it is the close connection in the intervention-effect relationship that can be proved or disproved. The **interrupted time series (ITS)** design involves a treatment group and a series of measurements (e.g. 4-4) before and after the intervention. The reason for multiple measurements is that a single one is not reliable since before or on the day of the measurement an event affecting the results may happen. By periodical measurements it is hoped that the event will not be present every time. The picture obtained will be even more precise if the series of measurements is done for both a control and a treatment group. (Paraho (2006), Lázár (2009); Lehota (2001)

Validity expresses how accurately a well-implemented research corresponds to reality. Internal validity concerns the adequacy of the causal relationship observed while external validity expresses how the results acquired can be generalized for the population.

During the assessment of internal validity, numerous factors, which contribute to the correspondence between conclusions and reality, need to be considered. Such factors are: 'exhaustion', i.e. participants alter independently in time influencing results; the repetition of tests may influence performance too, e.g. results in post tests may be more accurate; differences in instrument sensitivity; a positive change is more likely in those with extreme parameters, changes of the study venues; according to the Hawthorne effect participants change when they know they are observed; psychic factors by the placebo effect; participants dropping out; effects affecting the treatment group may spread over to the control group if they can communicate; the participants' willingness to cooperate may also influence results.

1.4.9.1.1. Questionnaire-based survey

The questionnaire-based survey is the most common primary research and information acquiring technique, suitable for descriptive, explanatory and exploratory purposes. It is a method often used in the field of health science research, especially in researches on concepts like satisfaction, pain, stress and quality of life. Moreover, information can be gathered about attitudes, knowledge, opinions, expectations, experiences and the behaviour of patients and carers. Its *advantage* is that it is relatively easy to implement and it does not normally burden respondents, and questionnaires properly designed and filled out may deliver relevant information to researchers. In certain research topics it is often the only applicable possibility. Its disadvantage is researchers' and respondents' subjectivity, occasionally the lack of sincerity.

The first step in questionnaire construction is determining the scope of the necessary information according to the research goals followed by arranging the questions in groups by logic and content. The administration mode and the questionnaire type need to be decided upon. The order of the topic groups is established depending on the administration mode, the questions are formulated (wording, scales, answer categories, tables, etc.) and possible mistakes are detected within a pilot survey. (Parahoo (2006), Lehota (2001))

Conceptualization (the definition of related concepts) and operationalization (creating 'operations' - making abstract concepts researchable) can facilitate *determining the information range*. Creating a research model helps researchers control the effects of factors for whose the investigation they have no or only limited possibility in the given situation.

The **questionnaire administration mode** determines the order, the structure and formulation of the questions profoundly. According to the person filling out the questionnaire, there is the

so-called **face-to-face questionnaire administration**, where an interviewer presents the previously formulated questions, interprets them if need be, and records the answers. The advantage of the method is that information shortage can be avoided but the disadvantage may be that respondents are less sincere. In the **self-administered** form the respondent him-/herself reads, interprets and answers the questions. Its disadvantage is that in the case of inappropriate questions and/or problems in interpretation filling out is insufficient. In **questionnaire administration on the telephone** interviewers call interviewees at their homes or places of work. **Questionnaire administration on the Internet** is considered aided administration since programming allows warning respondents about wrong or missing answers, and it follows the logical connections and moves between questions automatically. Its disadvantage is that those without computers/Internet are left out of the survey and computer users are not always willing to participate either, which may mean a great distortion of the sample.

Today **validated questionnaires** are available on many topics as appendices to publications or on the Internet free of charge or in other sources of scientific literature in their entirety together with assessment instructions. References to further questionnaires are found in the methodological sections of original publications. In such cases it is possible to ask the author for the questionnaire itself and/or authorization to use it. In the case of a questionnaire in another language one may translate it him-/herself but for a bigger survey it is advisable to have a correct linguistic adaptation. (Three independent persons translate the questionnaire into the target language and then, based on the three translations they create a common version, which a bilingual translator translates back into the source language. If there is no significant difference between the two source-language versions, the adaptation is finished. The finished version is then read by 5-10 independent people, according to whose comments the questionnaire may still be corrected.) Examples for this can be read in the validating study of Stauder, Konkoly's (2006) questionnaire on detected stress and in that of the effort - benefit - imbalance questionnaire by Salavecz et al. (2006), which show the process of adaptation. Validated questionnaires - apart from a few exceptions - do not contain sociodemographic or other questions concerning the subject. Thus, they always need to be complemented by these. In the case of using measuring instruments one must also have the assessment criteria for interpreting the results. Lakyné Pomázi (2008), Parahoo (2006), Lehota (2001), Pakai and Kívés (2013)

A) Using indices and scales

In quantitative researches mostly complex indices are suitable for exploring attitudes, opinions, statuses, etc. They are the so-called indices or index values, by which the characteristics of the subject examined can be established. For example, the 20-item abridged version of the Minnesota Satisfaction Questionnaire (Martins, 2012) is suitable for measuring the satisfaction levels of hospital staff. The answers are to be indicated on a five-point Likert scale, where 1 is very dissatisfied and 5 is very satisfied. Finally, the numeric values of the answers are added up or averaged, and lower scores will show lower satisfaction levels. For measuring patient satisfaction the Long-form satisfaction questionnaire (PSQ-III), whose current long version contains 50 (18 in the short one) items, can be used. It measures the level of satisfaction on a five-point scale in several dimensions, e.g. general satisfaction 6 items (6-30 points), technical quality 10 items (10-50 points), etc. According to the scores patients' satisfaction levels are comparable at the levels of wards or institutions. Questionnaires on the quality of life are meant to measure the effectiveness of care too, e.g. EQ-5D, SF-36, which also characterize the respondents' statuses by index values.

While indices explore complicated phenomena, **scales** show the inner structure of the phenomenon measured. Assessment scales may indicate the presence or absence of something. *Graphic scales* (simple lines usually) show the intensity of a judgment or opinion; *numeric scales* express judgement on something by numeric values. So-called semantic differential scales measure the intensity of dimensions of phenomena and processes between two opposite statements by a graphical scale. At the ends of the scales there are opposite characteristics, such as bad-good, friendly-unfriendly, satisfied-dissatisfied or difficult-easy. The continuity between the two extremes is usually represented by a line consisting of seven segments. The *Likert scale* can be used for measuring statuses and opinions when the respondents have to indicate the degree of their agreement about a statement. This scale always has five degrees and it consists of statements reflecting several different opinions. The Likert scale is useful for screening by asking questions of an inverse nature. In a *visual analogue scale (VAS)* records appear along a line between two points, granting the respondent more freedom in marking the most characteristic position. The line can be either horizontal or vertical and of various lengths. The vertical form is preferred because it represents the pairs of opposites, e.g. more-less, best-worst, etc., more directly. It is applicable for measuring, e.g. physical activity, exhaustion, and the various forms of pain.

While preparing a self-constructed questionnaire one can still rely on using unchanged questions from earlier investigations, e.g. smoking habits can be measured in a form occurring in representative surveys on the health status of the population. This allows asking the best questions at the measurement level achievable, furthermore, it makes later comparisons with own results also possible. What was said above about constructing questionnaires does not constitute a compulsory rule to be used in every situation but considering it takes one closer to achieving one's goal at any rate.

- The ***main characteristics of the target population*** (e.g. age, social status, knowledge, education, etc.), which may greatly determine the formulation of the questions and the construction of the questionnaire, need to be considered.
- The ***questions should be clear and unambiguous***, comprehensibly formulated. If a researcher is at home in a given field, even complex questions may seem simple, and the other way round, when only superficially deliberated, the questions will not be precise enough.
- ***One should not use complex sentences and foreign terms.***
- ***Its tone should be polite and neutral.***
- ***Each question should aim at one thing at a time***; in the case of questions including 'and' and 'or' respondents do not know which question to answer.
- The ***respondents should have enough information*** to answer the questions. The questions should focus on up-to-date issues relevant and close to them.
- And they ***should not be beyond their knowledge and experience.***
- Respondents should be ***willing to answer***. People are anxious about what they disclose because they are afraid of future consequences or because they consider issues too intimate or shameful.
- ***One should use short questions*** as respondents might not start studying a question if they do not understand it. A good question is easy to read and understand and can be answered quickly without difficulties. This is especially important in the case of self-administered questionnaires.
- Many respondents overlook *the word 'not'* and they answer accordingly. Thus, ***negative questions should be avoided.***
- ***Suggestive questions*** that prompt respondents to answer in a given way (*Do you agree that ...*) ***should be avoided.*** There should be an option to refuse to give an answer, by

using phrases, e.g. *'I have no opinion'*, *'I do not know'* or *'I would not like to answer'*. Parahoo (2006), Babbie (2008), Lehota (2001)

Questions can be grouped according to various aspects. *According to their functions* one can distinguish *'main questions'*, directly concerning the research topic and *'complementary questions'*, which help assess the results from the main questions (e.g., demographic data and introductory questions).

They may also be grouped according to the choices of answers: *single- and multiple-answer closed-ended questions*, where the answers are to be selected from given options. The advantages are that the respondents' writing skills are not as important, the number of answers received is higher, the respondents have an easier task, more questions can be asked and the answers are more uniform and easier to process. For closed-ended questions the *principle of entirety*, according to which the entire range of possible answers must be covered, is essential. If this cannot be done, the 'other' option at the end of the closed-ended questions may be used (*semi-open or semi-closed question*). *According to the rule of exclusivity* there must not be any overlapping of answer choices, e.g. in the case of aged 18-30 or aged 30-45 somebody aged 30 could choose both options. The closed-ended question presented so far belong to the so-called *selective (or multiple choice) questions*, where the number of options is high, at least three. In the case of *dichotomous (yes/no) questions* there are only two choices (e.g. Have you ever used the Internet? Yes/No). In such a case a so-called neutral answer may be offered (e.g. 'no opinion' and 'no answer'). Further help may be provided for complying with certain conditions. (e.g. Are you going to vote? Yes - if ...)

In the case of *single-answer questions* only one of the options offered may be chosen. Consequently, if a respondent selects more than one answer, the question cannot be taken into account. In the case of multiple-answer questions several of the options may be chosen. A special version of that is the ordering question, where respondents have to order the options according to some criteria.

Open ended questions are answered by the respondents in their own words. They are informative and provide more freedom for expressing opinions. Their advantages are that they are easy to create, do not suggest respondents answers and the answers received can help formulating closed-ended questions. Their disadvantages are that they require more time, effort and a higher level of writing skills from respondents and do not allow a high number of questions and the processing is more complicated and time-consuming. Open ended

questions are recommended, e.g. if one is interested in the respondents' opinions and ideas without influencing them with options offered. They can also be applied in the case of questions eliciting specification, justification, arguments, suggestions, checking knowledge, and also, if it is impossible to comply with the rules of entirety and exclusivity. They are often important for complementing closed-ended questions (e.g. 'other', 'please, justify, 'for example').

According to their orientation questions may be *indirect* or *direct*. The purpose of indirect questions is to deduce opinions, attitudes, interests or knowledge with the help of given categories. Concerning income, for example, the tool also used in sociological research is more advisable: do they possess certain things, is it a problem to buy food and/or pay the bills. By direct questions one asks for the required information, e.g. education, marital status, etc. In exploring areas which may greatly affect the respondents, and answering them may be unpleasant, concern intimate issues or death or other negative emotions they should be used with great care.

B) Questionnaire construction

Besides the aspects of content, the appearance and construction of the questionnaire and the sequence of the questions may also affect achieving the goal especially in self-administered forms. A questionnaire must always be organized and well-arranged.

Self-administered questionnaires must be lead in by *instructions for filling in*. They contain the introduction, the purpose of the survey, instructions for filling in, motivation for answering all the questions, the considerations of data protection, anonymity and finally thanking.

The *sequence of the questions* may affect how consecutive questions are answered by the respondents. For example, if a respondent recalls a positive experience related to his/her colleagues, he/she may value his/her relationship with them more positively in a later question. The sequence of the questions may differ for self-administered questionnaires and those administered by an interviewer. In self-administered surveys some easy warm-up questions are followed by the main questions and the demographic questions come at the end. In the case of an interviewer he/she must persuade the respondent to participate, so he/she starts with the demographic data and after establishing the relationship he/she can turn to the main questions. If questions concern past, present or future statuses, it is advisable to arrange these in a structure, would aid completion.

Even in the case of the most careful questionnaire construction there is a risk of error. Thus, the administration of a test is necessary. Fundamentally three types of errors are distinguished: *formal errors* (typos, spelling and editing errors), *errors of content* (some questions cannot be interpreted, are superfluous or there are no answer options) and finally *logical errors* (incoherent numbering of questions, irrelevant answer options), Respondents may also be asked for opinions and comments about the questions. Measuring the time may also be a good idea if the time available for administering the questionnaire is limited (e.g. school class).

1.4.9.1.2. Focus group research , interview

Similarly to other qualitative research methods the goal of research by focus group interviews is also exploration, understanding and expanding knowledge. The method provides possibilities for a deeper understanding of the problems examined and the attitudes influencing human behaviour, getting to know various phenomena and the analysis of collected opinions, attitudes, beliefs. Focus group investigations carry out a detailed and thorough exploration of the area examined and use a sample focusing on the given research topic, in which representativeness is not an objective.

Usually 6-12 people participate in focus group researches. In this interview technique direct communication takes place not only between the interviewee and the researcher but with every group member. Normally only the major groups of questions are determined; there is no previously set concrete sequence of questions, since the goal is to find out about individual peculiarities and the opinions formulated in the group. An important feature of focus group researches apart from the continuous interaction is that besides respondents' concrete answers the comments, the gestures and the debates that evolve also carry valuable information. (Héra, Ligeti 2005)

In focus group interviews the effects of group dynamics are also important. The environment of a group usually facilitates and encourages spontaneous contributions by the group members. A further advantage of the group effect is that the experience and opinion of a group member may help the dynamics of the conversation and may encourage others to express their own opinions.

The researcher conducting the group interview is the moderator. The moderator is the coordinator of the conversation; his/her task is to facilitate a conversation in which there is a balanced, free any open exchange of opinions among the group members. All this should

happen in an atmosphere in which respondents do not feel inhibited and open up in front of one another. (Babbie, 2008)

Focus group interviews can also be observed from the 'outside', since the conductor of the research gains an insight into the way of thinking of the members of the group and observes the manifestations of their attitudes, preferences and aversions through a large detective mirror.

Focus group interviews go on for 1.5-2 hours at a time. Focus group interviews, as mentioned before, are always conducted by an experienced moderator or two moderators in dual moderation. Audio and video recordings are made of the interviews with the participants' written consent. Detailed minutes are written from the audio materials and they are processed by using content analysis software these days. The most well-known of these software programmes is atlas.ti, that analyses narrative texts.

1.4.9.1.3. Secondary research methods

Primary data are collected by a researcher in order to solve a particular problem (the major methods for this kind of data collection were presented above). In many cases, however, primary data collection may be expensive and time-consuming or even impossible. Secondary data have been gathered previously for solving another problem or have been recorded in the course of everyday work. Secondary data provide numerous *advantages* over primary data; besides easy availability databases are able to manage and make available such topics and amounts of data that could not be done by any primary method. The greatest disadvantage of secondary information is that data become outdated relatively fast, and it is not sure that one finds suitable secondary data for every question to be answered, and it may not always be possible to select the data suitable for the given purpose from the huge amount of available information in order to answer the question examined.

Revising and analysing the secondary data first and only going on to the primary method if the secondary sources have been exhausted is a useful approach. For instance, if national data show that women do not participate in screening, the reasons behind this may be investigated by a questionnaire survey.

Secondary data may be *internal data*, which are produced in the course of the operation of the institution related to management, finance or medical professional issues. Nowadays such data are mostly available electronically, which makes their further use a lot easier. Some of

the so-called *external databases* get their data from other data providers (e.g. the statistical agencies of certain countries) or collect, organize, process and publish them themselves.

When using databases, one needs to know the *accuracy of the data* (today's databases strive for reliable, precise and unified data collection and analysis), how up-to-date the data are and for what purpose they were originally gathered. An important element of content is the characteristics of the key variables, e.g. what categories, measures, basis of reference were used and what area or period they refer to.

A) Document analysis

In the document analysis method researchers analyse already available documents and data to explore a problem according to a previously defined system of criteria. Document analysis can be carried out for several purposes; it may help formulate hypotheses in the enquiring stage of the research, but it is also suitable for collecting and analysing data and reaching conclusions in the main part of research. It is applicable as an independent method, but may also be combined with other research methods, e.g. experiments, questionnaires, observations and case studies. During document analysis many official documents (medical charts, medical registry sheets, medical and/ or care documentation, final report, expert opinions, statistical data of clinic/hospital/ward) may be used but diaries and letters containing personal information may also be the subject of study. It is worth remembering that the documents above are not necessarily produced for health science research. Thus, their research ability needs careful consideration, moreover, the protection of data must also be guaranteed. Prior to document analysis it is necessary to obtain the written approval of the head of the given unit or occasionally the patients themselves. For authorisation purposes the principles of data handling and anonymity also have to be defined. During the preparation of the research plan some important aspects are worth taking into account.

- *Are the data to be studied available?* It may occur that the document to be investigated contains a data field that is important for the research but actually it is not, or only occasionally, filled in at the various sites involved in the study. Before the study it is advisable to enquire on the premises, to have a look at the selected documentation and then to create a unified system of criteria.
- *Is the selected document genuine, objective and reliable?* There are data which may be measured in practice several times daily, e.g. vital parameters. In such a case it must be decided which values will be processed.

- *How is the data processed?* In a quantitative or a qualitative way? Document analysis as a data collection method is one of the qualitative methods, but during the content analysis of medical documentation information containing not only qualitative but also quantitative data is also processed, e.g. patients' laboratory results. During the survey one has to make sure if, in the case of several institutions/wards/departments to be examined, the necessary data are recorded in the same way/form/categories.

B) Health databases

Data bases provide researchers or others interested with information that allows access to data collected and published outside the given institution at county, regional, national, European or even worldwide level.

According to the databases the information may concern various indices, such as *medical professional* information (disease data, information related to diagnosis or treatments, occasionally patient data), *public health* data (incidence, prevalence, mortality, morbidity, risk or lifestyle factors), *environmental or public health* data and *data related to finance* (income, expenses, payment of contributions, etc.)

1.4.10. On-line health databases

1.4.10.1. Hungarian Central Statistical Office (KSH)

Opening page: <http://www.ksh.hu/>

The KSH is a professionally independent government agency that processes official data related to the social, demographic and economic situation of the country. Its responsibilities include planning data recording, processing, storage, analysis and publication.

Upon clicking on a theme in the start page one can select the required data set and clicking on that will display the hits. (Figure 2)



Figure 2 Themes of KSH and the available data tables

The table collection of ready-made tables (STADAT) contains the most important data and indices collected by KSH or acquired from other organizations. Regional data are displayed broken down into counties and regions while the most important international data are shown related to the members of the European Union and some other countries. The tables can be downloaded and printed free of charge (also in Excel format) (Figure 3).



Figure 3 Accessing KSH STADAT data tables

For comparing nations and regions annual and mid-year indices are available, while data tables from EUROSTAT provide data about the EU countries, the USA and Japan on a wide range of topics. The *interactive graphs and maps*, for example, present certain indices broken down into nations and regions. (Figure 4)

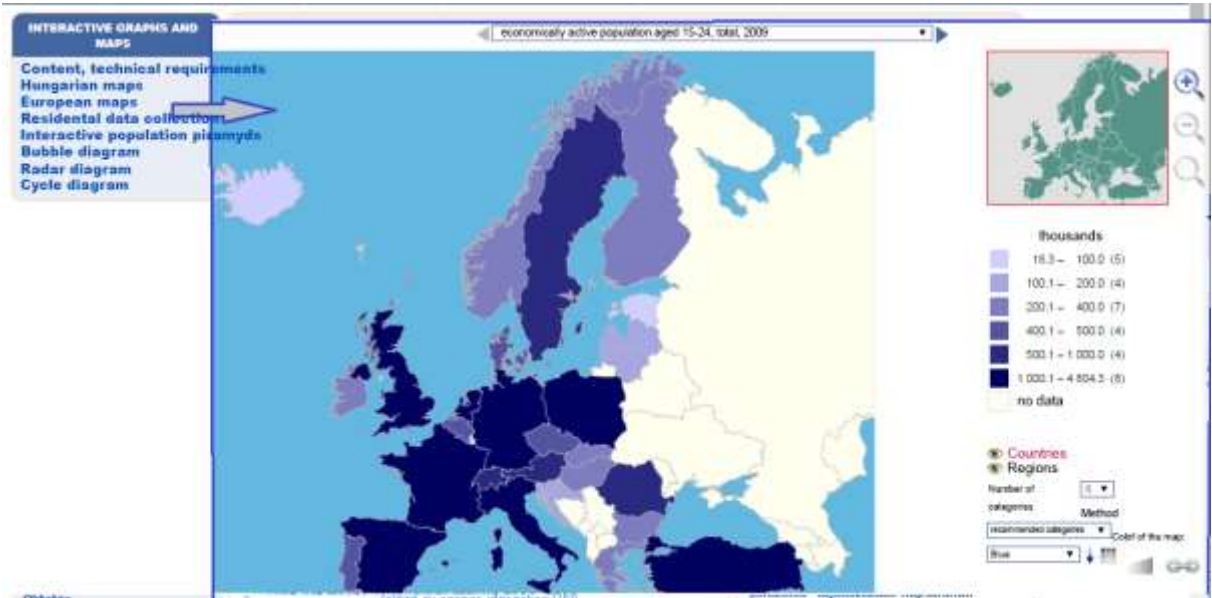


Figure 4 interactive graphs and maps - map of Europe

1.4.10.2. National Health Insurance Fund of Hungary (OEP)

Opening page: <http://www.oep.hu>

It collects data nationwide primarily for funding purposes concerning, among others, general medical practice, outpatient care, home care, dental care, active and chronic in-patient care, transport of patients, medication, medical accessories, medicinal baths, sick leave and permanent disability. It also provides patient-level (TAJ) detail. In the start page one can select the public or the professional start page. (Figure 5) In the public page mainly data of public interest can be accessed, e.g. the contact data of government offices and the types of care supported by health insurance in Hungary, Europe and overseas.



Figure 5 The public and professional start pages of OEP

The page of the General Department of Finance of OEP can be accessed from the menu of the professional page (*gyógyinfok*). Its scope of activities include curative and preventive care and the organization of economic processes related to that, developing and coordinating the use of code systems, collecting sectoral data, preparing databases and filling them with data.

From the *Statistics, reports* menu one can also access, besides the performance data of inpatient care, information on the hospitals' patient and outpatient numbers and reports in an annual breakdown. (Figure 6)

The screenshot displays a software interface for accessing statistical data. The main window is titled "Statistical data" and shows "Inpatient specialized care's performance data" for the year 2010. A dropdown menu is open, listing various indicators such as "Case-mix index", "Word care case", "Accounted nursing day", "HBC case", "Normative day weight number", "Chronic nursing case", "Chronic accounted day", "Weighted chronic day", "Normative number of beds", "Necessary active number of beds", "Necessary chronic number of beds", "Overall HBCS-cases", and "Overall data". A table titled "Institution providing case" shows data for 21 counties, including Budapest, Baranya, and others, with columns for county name and numerical values. The interface includes a sidebar with navigation options like "Functions", "NEWS", and "STATISTICS, REPORTS".

COUNTY	BUDAPEST	BARANYA	BÁCS-K	BÉKÉS	B-A-Z
01 Budapest	389883	1290	7597	2722	6018
02 Baranya	565	94021	2477	84	107
03 Bacs-Kiskun	445	87	106255	268	43
04 Bekes	141	6	67	71627	21
05 Borsod-Abaúj-Zemplé	375	16	46	49	155122
06 Csongrad	492	86	11069	10040	113
07 Fejer	732	100	1523	61	102
08 Gyor-Sopron-Moson	288	43	70	36	108
09 Hajdu-Bihar	856	42	417	1154	5749
10 Heves	264	18	20	27	894
11 Komarom-Esztergom	1135	32	63	65	105
12 Nograd	176	2	15	9	93
13 Pest	9872	49	518	136	246
14 Somogy	604	1212	160	35	37
15 Szabolcs-Szatmar-Be	311	12	12	19	2530
16 Jasz-Nagykun-Szolno	239	5	183	1021	54
17 Tolna	94	1685	736	10	12
18 Vas	129	14	25	5	23
19 Veszprem	569	91	82	28	44
20 Zala	265	53	42	15	41
21 Total	407435	98864	131377	87411	171462

Figure 6 Accessing verbal statistical data

The aggregate inpatient data can be accessed from the *on-line databases* menu. In the pop-up window one or more indices, which can be seen in an aggregate form at county, regional or national levels, can be selected (Figure 7)

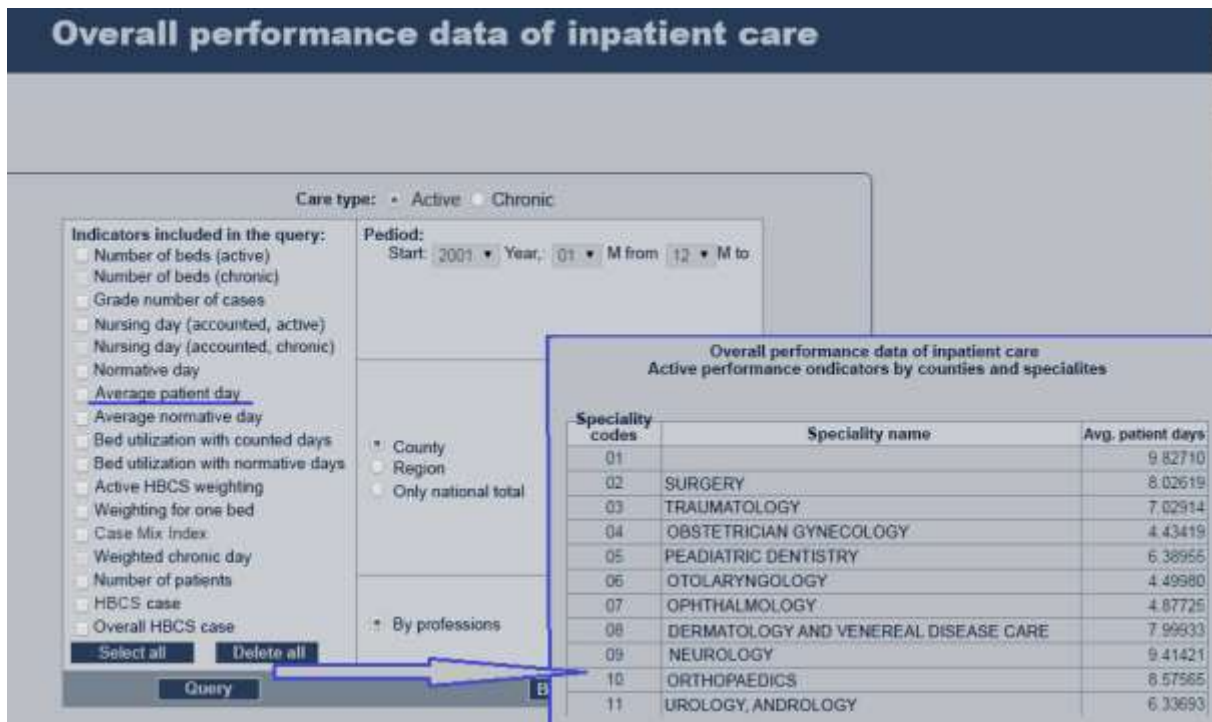


Figure 7 Accessing the aggregate performance data of inpatient care

1.4.10.3. National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI)

Opening page: <http://www.eski.hu/>

Several databases are available in the GYEMSZI webpage.

The **basic data of the healthcare system** are accessible from the *Health information, data* menu point (Vital statistics 1950-2009; Health insurance contributions 1993-2011; Activity of the health care delivery system 1994-2009; Revenues and expenditures of the Health Insurance Fund 1993-2011). First the table of contents appears in Excel format, then the data are accessible by clicking on the selected item. (Figure 8)



Figure 8 GYEMSZI - accessing the basic data of the healthcare system

In the website of the **Internet-based Hungarian Health Datawarehouse (IMEA)** one can access the *Regional Health Datawarehouse Online (REA)*, the *Hungarian Health Datawarehouse Online (MEA)* and the *data reported to the OECD and the HFA* in various themes. In the case of the latter two, national data are available. Thus, for the required index only the year has to be selected. (Figure 9)

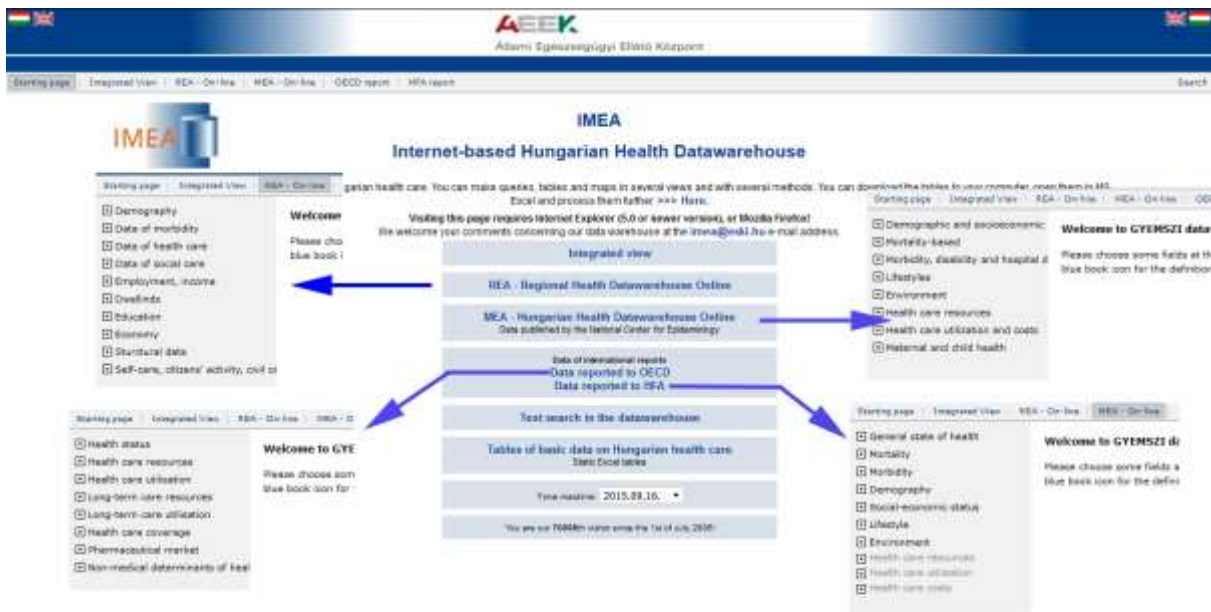


Figure 9 Data sources and their indices accessible by the Internet-based Hungarian Health Datawarehouse (IMEA)

In the REA and MEA databases the required data indices can be selected on the left-hand side, then data can be retrieved for counties, regions and/or national aggregates, giving the years too. The table of hits appears on the new page. (Figure 10)

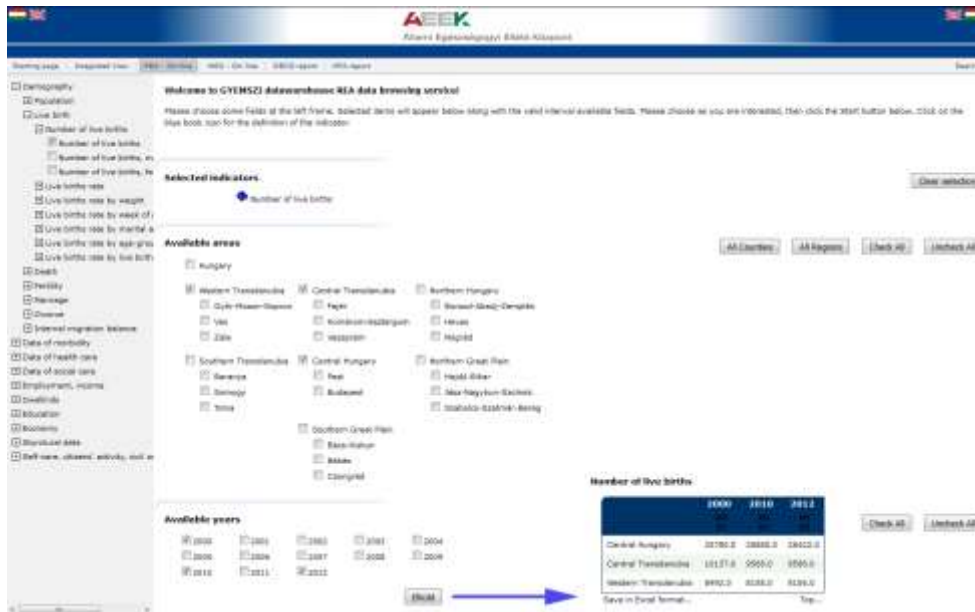


Figure 10 The search interface of the REA database and its table of search results

The Thematic Health Datawarehouse (TEA) is accessible from the eski.hu start page. After free registration one may enter the database of GYEMSZI. The selection of thematic health data and themes is done in the window on the left (in-patient care, outpatient care, hemodialysis, CT/MRI case financing), then the indicator is chosen and parameters can be given for the type of table to be created. (Figure 11)



Figure 11 The search interface of the TEA datawarehouse

From the GYEMSZI website the *HealthOnline* site is also accessible, where the Hungarian summaries or the whole documents of reports are available in many topic areas. (Figure 12)

Topics

- Demography
- Features of health care systems
- Health care costs
- Funds and list of services
- Resource allocation
- Public health
- Primary care, outpatient specialized care
- Inpatient care
- Rehabilitation and long term care
- Emergency medical services
- Drugs
- Health care workers
- Quality management
- e-health care
- Health care reforms
- Health policy
- Health statistics**
- EU Health
- Country information
- Events
- Useful links
- EU member states
- Link collection
- World Health Organization (WHO)
- OECD
- E-mail
- Editors, contact

Questionnaire - We would like to know your opinion!

HealthOnline - Health statistics

Recent articles	Topic	Date
OECD Health at a Glance 2013 >>	Health statistics	11-12-2011 14:45:01
Franciaországban viszonylag kevés az MRI-berendezés >>	Health statistics	02-05-2013 14:27:31
Health at a Glance 2012 – Európai helyzetkép >>	Health statistics	30-11-2012 14:47:04
OECD: Hogyan élünk? A jólét mérése, 2011 >>	Health statistics	15-12-2011 13:52:02
OECD egészségügyi adatok 2010 >>	Health statistics	29-06-2010 17:31:55
Az egészségügyi regulációs díjak hatásának statisztikai felmérése Csehországban >>	Health statistics	19-01-2010 16:22:29
Bizottsági jelentés a Gazdasági Tejesítményről és a Társadalmi Haladásról (Stiglitz-jelentés) >>	Health statistics	03-11-2009 11:48:26
OECD Health Data 2008 - Magyarország >>	Health statistics	22-09-2008 14:28:42
Magyarország a „Health at a Glance” OECD kiadvány tükrében >>	Health statistics	28-11-2007 15:11:50

[g recent articles](#)

[Previous articles >>](#)

Figure 12 The topic areas of the *HealthOnline* site and its current articles

- The **patient number data** are accessible from the Data, Statistics, Codes menu in the main page with guiding menu items helping the search. (Figure 13)

GYEMSZI
Gyógyszerészeti és Egészségügyi
Minőség- és Szervezetfejlesztési Intézet

1054 Budapest, Hold utca 1. ✉
Tel.: 1 354 5326, 1 354 5327
Fax: 1 266 9710

About us **Data, statistics, codes** **Research** **Health politics** **Reference library - MOB**

- Fundamental
- Sectoral wage increase
- Pirce information
- Wage statis-
- Investment statistics
- IMEA data
- Code systems
- International dataservices
- TEA data
- Patient registration data**

Inpatient's overall data **Outpatient's overall data**

1. Indicator **2. Filter options** **3. Setup axis** **4. Start query** **5. View results**

Period Hospital Department Profession

- Actual day
- Active case number
- Weight number
- Long nursing day**
- Intense long day
- Active care fee
- Chronic case number
- Days of chronic days
- Weighted days of chronic days
- Chronic care fee

Stalográfia

Figure 13 Searching for patient number data

1.4.10.4. National Cancer Registry

Starting page: <http://www.oncol.hu/rakreg/stat3/index.html>

The National Cancer Registry is a population-based registry system operated by the National Institute of Oncology. The centre gathers data with quality control from hospitals. It publishes annual reports containing data of various tumour diseases, broken down into sex, age group and region. On the start page of the National Institute of Oncology in the *Medical attendance* menu point clicking on the departments option one comes to the *National Cancer Registry and Biostatistical Centre*. At the bottom of the following window one can reach *Data service*. Among the filtering options one can search the data of one or more diagnoses, years, counties and age groups. If one selects the *In separate table* option, the data of particular years, age groups or counties are displayed in separate tables. (Figure 14)

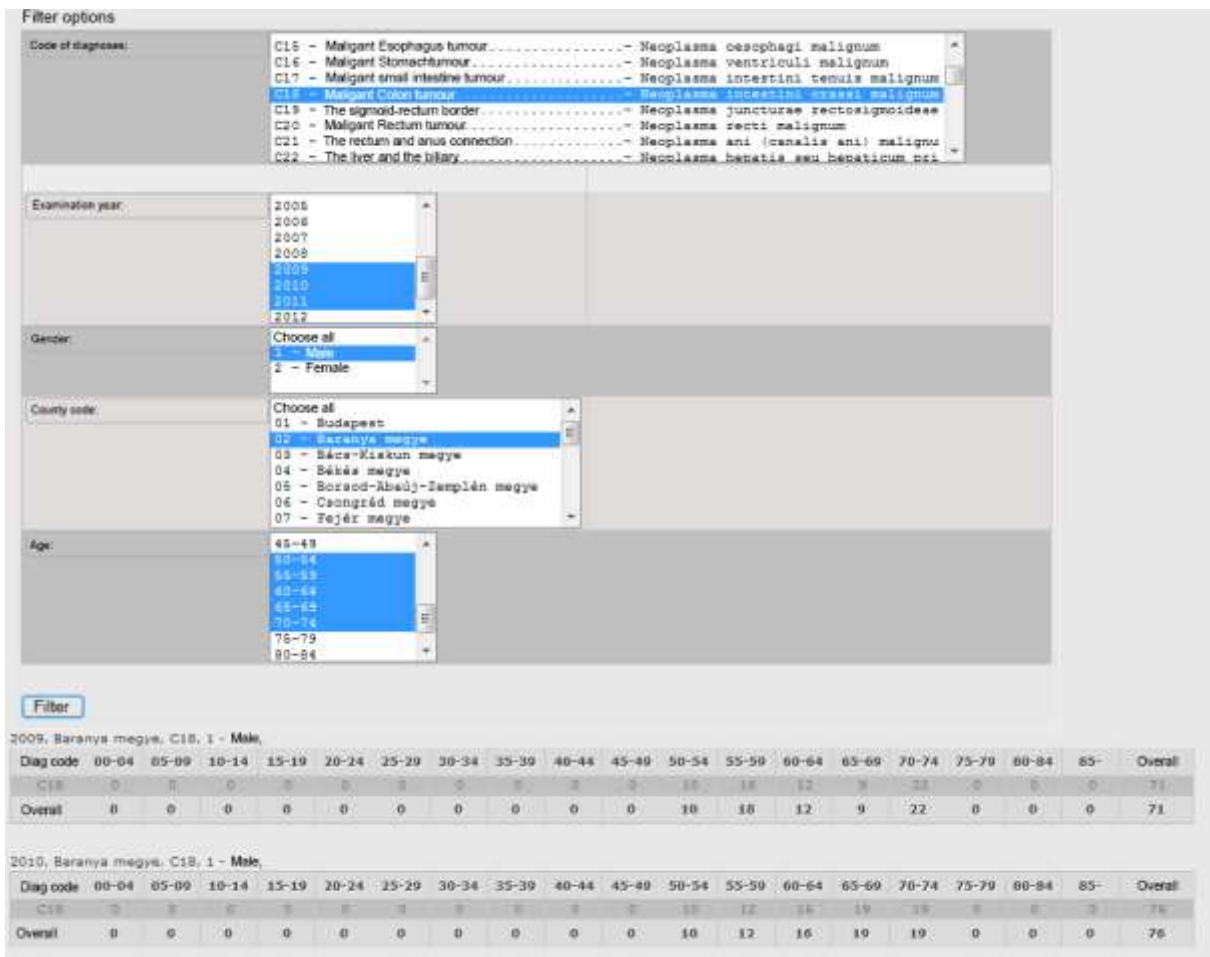


Figure 14 The search interface of the National Cancer Registry and its table of search results

1.4.10.5. UNICE (United Nations Economic Commission for Europe)

Opening page: http://www.unece.org/stats/stats_h.html

On the UNICE website among many other topics one may access a great amount of information related to healthcare and health under the *Gender Statistics* menu. (Figure 15-16)



Figure 15 Topic areas displayed in the online search interface of UNICE

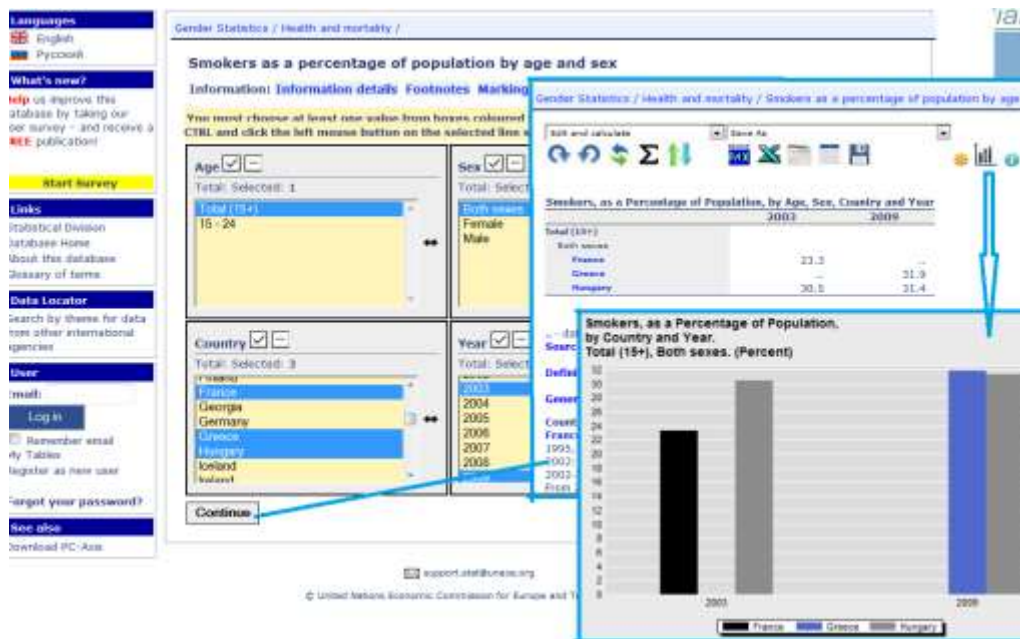


Figure 16 The data field, the search results table and the figure associated with the required indicator

1.4.10.6. **EUROSTAT**

Opening page: <http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/theme>

The Eurostat is the European Union's statistical office, whose responsibility is the compilation of statistics at a European level, which allows the comparison of countries and regions. It does not gather data directly; the data are provided by statistical authorities of the member states. Eurostat harmonizes the data and makes them comparable. The office was established in 1953 and its scope of activities keeps expanding; it makes data available on a wide range of topics for decisions affecting the Union. The themes appear within the Statistics menu but an A-Z search is also possible. (figure 17) After choosing the theme, by clicking the *database* the tables, which open after clicking the icon before the required variable, can be selected.

The screenshot shows the Eurostat website interface. On the left, a navigation menu for the 'Health' theme is visible, with 'Database' highlighted. The main content area shows a tree view of the 'Health status (hlth_state)' dataset, with 'Healthy Life Years (hlth_hly)' selected. A blue arrow points to the 'Database' link in the left-hand menu.

Figure 17 Data search related to a Eurostat theme

appsso.eurostat.ec.europa.eu/hui/show.do?dataset=hlth_hly&lang=en

Important legal notice
4.184.3-20140326-2467-#000_Full

Explainers facts (metadata) Information Download Refresh Bookmark Delete Help

Healthy Life Years (from 2004 onwards) [hlth_hly]

Last update: 08-10-2014

Table Customization

	2004	2005	2006	2007	2008	2009	2010	2011
European Union (28 countries)	-	-	-	-	-	-	-	62.7
European Union (27 countries)	-	62.5	62.5	62.6	62.2	62	62.7	-
Belgium	78.4	82.3	83.2	83.5	84.2	83.7	82.6	83.8
Belgium	-	82.3	83.2	83.5	84.2	83.7	82.6	83.8
Belgium	-	82.3	83.2	83.5	84.2	83.7	82.6	83.8
Czech Republic	-	60	60.5	63.3	63.4	62.7	64.3	63.6
Denmark	69	68.6	67.2	67.6	61	68.4	61.4	59.4
Germany (until 1990 f)	-	54.8	55.3	56.6	57.7	58.1	58.7	58.7
Estonia	52.8	52.4	53.8	54.9	57.3	59.2	58.2	57.6
Ireland	64.2	64	64.6	65.6	65	65.2	67	68.2
Greece	63.5	67.4	68.1	67.4	66.1	66.8	67.7	66.5
Spain	62.7	63.4	63.5	63.2	63.6	62.2	63.9	63.8
France	64.3	64.6	64.4	64.4	64.6	63.5	63.4	62.6
Croatia	-	-	-	-	-	-	60.7	61.8
Italy	71	67.8	66.7	62.5	61.9	62.6	61.6	62.7
Cyprus	-	58.2	63.4	62.9	65.4	65.6	64.2	61
Latvia	-	52.2	52.5	54.1	54.6	56.2	56.7	56.8
Lithuania	-	54.6	56.5	58.2	59.9	61.2	62.4	62
Luxembourg	60.2	62.4	62.1	64.6	64.4	63.9	66.4	67.1

Figure 18 Table of search results for a selected indicator

1.4.10.7. European Health for All Database (HFA-DB)

Opening page: <http://data.euro.who.int/hfad/>

The HFA-DB provides data on basic statistics: demographic data, health status, factors determining health and risk factors as well as the utilization of healthcare resources and expenditures from 53 countries of the European Region of the WHO. It allows search by selecting countries or regions and the results can be displayed, according to one's wish, in the form of tables, graphs or maps and may be exported for further use. The service is available both off-and online. (Figure 19-20)

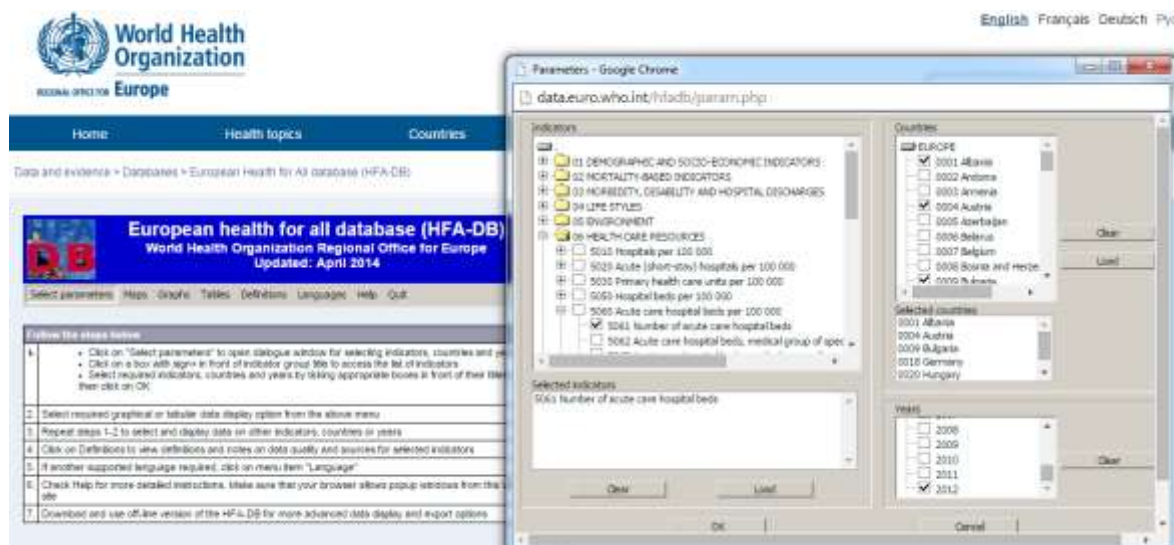


Figure 19 The search interface of HFA-DB

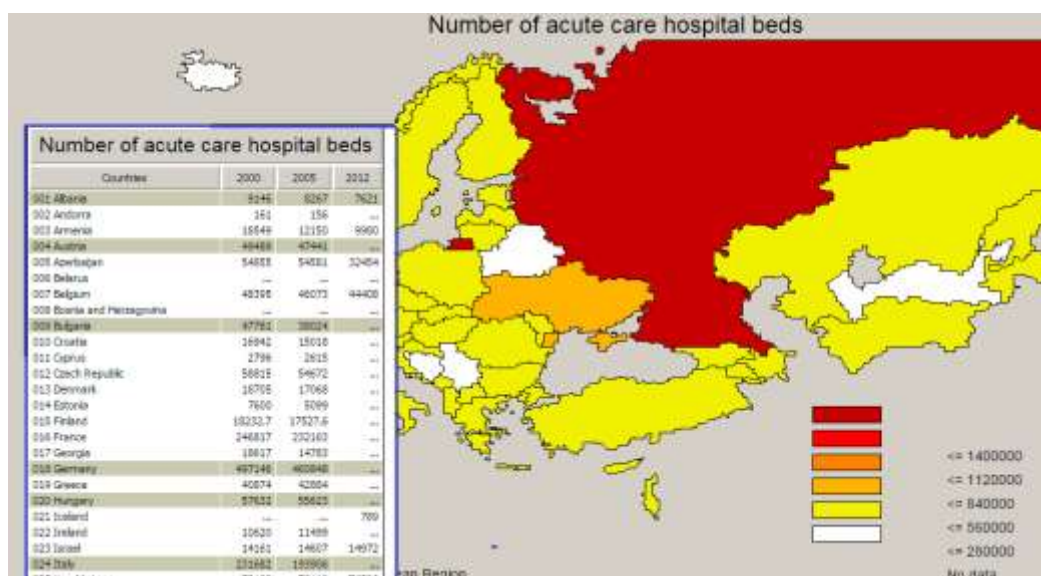


Figure 20 The options of displaying the results of searching the HFA-DB

1.4.10.8. OECD (Organisation for Economic Co-operation and Development)

Opening page: <http://stats.oecd.org/#>

In the search interface of the OECD the themes can be selected on the left-hand side. Via the drop-down menus of the themes numerous indices are accessible. Clicking the Customize menu point one can filter by variables, years or countries, the results can be shown in various file formats and graphical display may also be selected. (Figure 21)

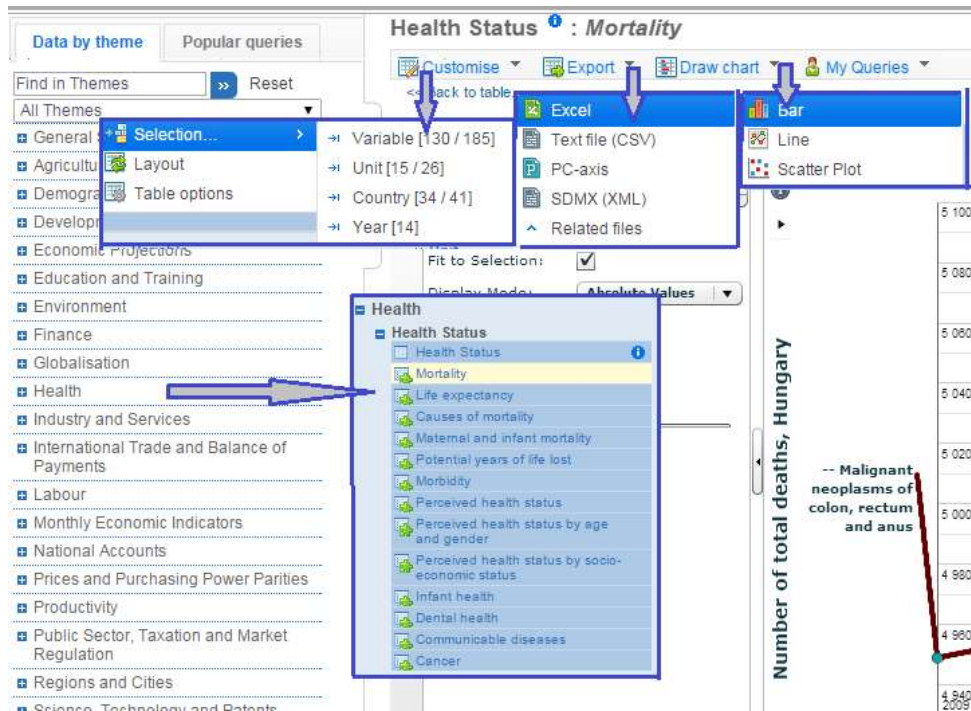


Figure 21 The statistical data search interface of the OECD



Figure 22 The search result table of the OECD

1.4.10.9. OECD Data Beta

Opening page: <http://data.oecd.org/>

Themes can be also chosen in the *OECD Data Beta* website, and the results appear in images or in charts as requested. By moving the cursor over the images the data labels appear but the data of the selected country can also be shown separately.

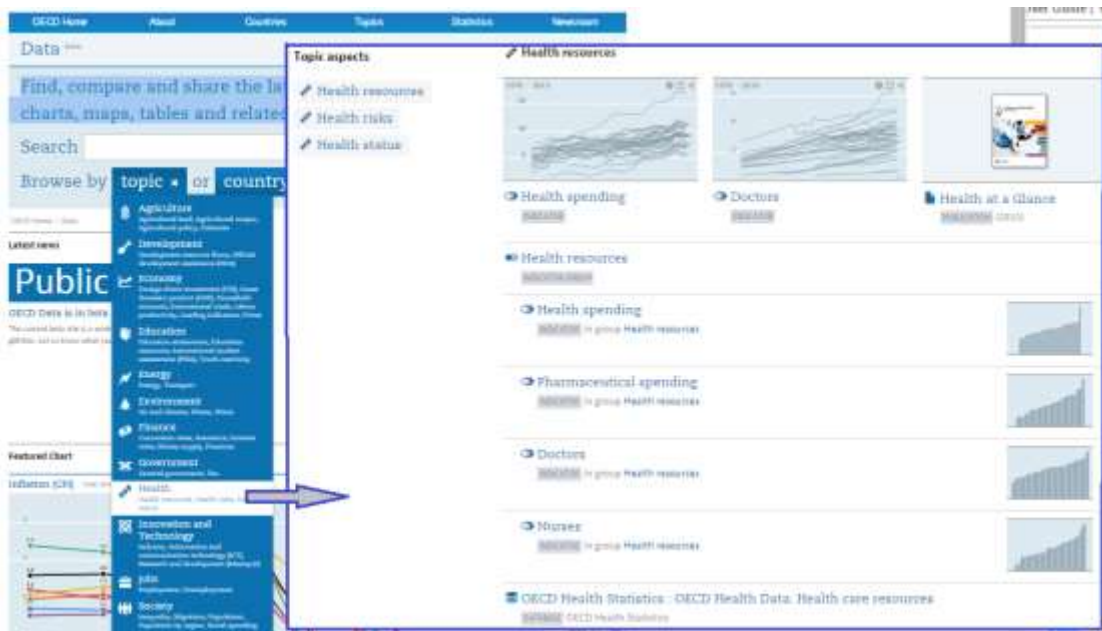


Figure 23 The search interface of OECD Beta

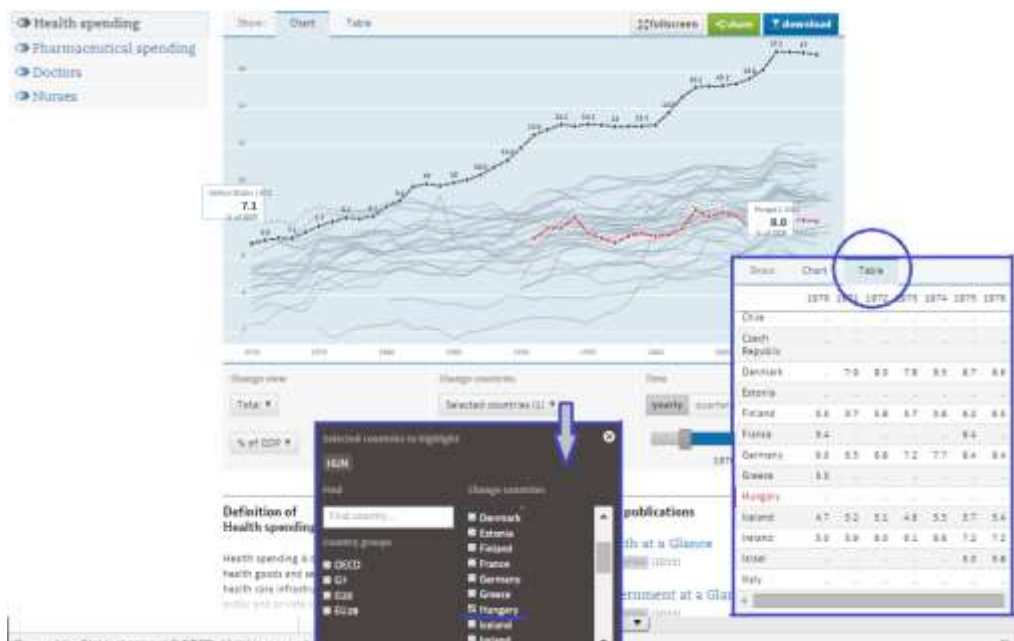


Figure 24 The OEDC Data Beta search result interface

1.4.10.10. Global Health Observatory (GHO) Data Repository

Opening page: <http://apps.who.int/gho/data/node.main>

The GHO database provides access to more than 1 000 health indices related to mortality, disease burden, child nutrition, child health, maternal and reproductive health, vaccinations, communicable and non-communicable diseases, risk factors and environmental health. In addition, it also makes the summarized annual reports of WHO member countries available. In its search interface the data of further sub-themes and indicators appear after choosing a theme. (Figure 25)



Figure 25 The search interface of the GHO and its table of search results

1.4.10.11. International Agency for Research on Cancer

Opening page: <http://www-dep.iarc.fr/>

The site provides access to databases worldwide in connection with tumour diseases. Via GLOBOCAN the latest (2012) information related to tumour diseases, morbidity and prevalence from 28 countries of the world are available. CI5 (Cancer Incidence in Five Continents) provides access to the incidence indices of tumour diseases via national and regional cancer registries. ACCIS (Automated Childhood Cancer Information System) provides information about children's tumour diseases and survival based on European cancer registries. The DIICC (The International Incidence of Childhood Cancer) informs about the incidence of childhood tumour diseases on the basis of cancer registries worldwide. The ECO (European Cancer Observatory) is a web-based tool for accessing data related to European tumour diseases for analysis and downloading. NORDCAN presents the morbidity and

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2. INTRODUCTION TO EPIDEMIOLOGY (I. BONCZ, R. VAJDA, ZS. HORVÁTHNÉ KÍVÉS)

2.1. THE HISTORY OF EPIDEMIOLOGY

Hippocrates (460 – 370 BC), the father of medicine studied, among many other things, the external and internal causes of diseases. He observed that certain diseases occurred in different geographical locations, e.g. malaria and yellow fever were much more common in swampy areas. He even formulated the difference between endemic and epidemic.

About 2000 years later, in 1662 *John Graunt (1620-1674)*, a London haberdasher analysed the weekly birth and mortality data of London in his work entitled *The Nature and Political Observations Made Upon the Bills of Mortality*. Besides other things, he also noted the higher rate of birth and mortality among men, the high infant mortality and the seasonal fluctuation of the mortality indices, which Hippocrates had also observed. He realized the importance of routine data collection for studying diseases, thus laying the fundamentals of modern epidemiology.

Natural and Political
OBSERVATIONS
Mentioned in a following INDEX,
and made upon the
Bills of Mortality.

By *JOHN GRAUNT*,
Citizen of
LONDON.

With reference to the *Government, Religion, Trade,*
Growth, Age, Diseases, and the several Changes of the
said **CITY.**

— *Nos, ne ut miratur Turba, labere.*
Centenas pariter Liberos —

LONDON,
Printed by Tho. Roycroft, for John Martin, Tenant *Albion,*
and Tho: Ducas, at the Sign of the Bell in St. Paul's
Church-yard, MDCLXII.

Figure 1

Title page of John Graunt's book

However, these new methods were not really used in practice over the following two centuries, until **William Farr (1807-1883)**, an English physician was appointed to establish the medical statistical department of the Central Office of Records in 1839. He organised the routine registration of the causes of deaths, which were published annually (Annual Reports of the Registrar General). He compared the mortality data of married and single people as well as those of people of various occupations. During his studies he introduced several new concepts and methods, e.g. the exact definition of a population exposed to a risk factor, the selection of suitable control groups and the examination of other factors affecting the illness (age, the length of exposure, general health status).

Two decades after the commencement of Farr's work another physician, **John Snow (1813-1858)** examined the origins and epidemic of cholera in detail in London. He discovered that cholera was spread by contaminated water by a mechanism then still unknown.

He also observed that the rate of mortality was especially high in those parts of London where the Lambert Company or the Southwark and Vauxhall Company supplied the drinking water. Both companies got the water from that part of the Thames where sewage from London had already greatly contaminated it. Between 1849 and 1854 the Lambert Company moved the place of water withdrawal to a part of the Thames where the river was still free of London's sewage. After that the incidence of cholera became considerably lower in the areas supplied by the Lambert Company compared to those serviced by the Southwark and Vauxhall Company.

Table 1 shows the mortality indices of the 1953-54 cholera epidemic in the areas of London serviced by the respective water supply companies. One can see that the mortality data per 100 000 residents are the highest in the areas where the Southwark and Vauxhall Company supplied contaminated water, they show an intermediate value in the areas serviced by the two companies jointly, while no deaths were recorded in the areas belonging to the Lambert Company.

1 Table 1 Mortality data of the London cholera epidemic

Waterworks	Population in 1851	Deaths by cholera 1853-54	Deaths per 1000,000 residents
Southwark and Vauxhall	167 654	192	114
Both companies	301 149	182	60
Lambert	14 632	0	0

John Snow also investigated the other conditions that might have influenced the spread of cholera, and he remarked that both companies provided water both to the rich and the poor, large and small houses and there was no differentiation in either the social or occupational statuses of those serviced. Thus, people were not placed in either of the two groups according to their social or material statuses but according to whether they received contaminated water from the Southwark and Vauxhall Company or clean water from the Lambert Company.

2 Table 2 *Mortality data of the London cholera epidemic*

<i>Waterworks</i>	<i>Number of houses</i>	<i>Deaths caused by cholera</i>	<i>Deaths per 1000,000 residents</i>
Southwark and Vauxhall	40 046	1 263	315
Lambert	26 107	98	37
Other parts of London	256 423	1 422	59

Snow investigated cholera cases and water supplies walking from house to house. Deaths caused by cholera in connection with the waterworks can be seen in table 2. On the basis of these data it became clear to Snow that the contaminated water supplied by the Southwark and Vauxhall Company was to blame for the outbreak of the cholera. Thanks to the measures introduced as a result of the discovery the number of deaths fell dramatically.

The map in Figure 2 was made by Snow in 1854 to illustrate that cholera was more frequent around the street wells supplying contaminated water. To prove his hypothesis the handle of the street well in Broad Street was removed, which put an end to the epidemic. The memory of stopping the epidemic is still safeguarded by a symbolic water pump without a handle at the crossing of Broad Street and Cambridge Street.

During his investigation Snow mapped the incidence and spread of the cholera and identified its origin. That means that presumably he was the first researcher to study all three components of epidemiology together.

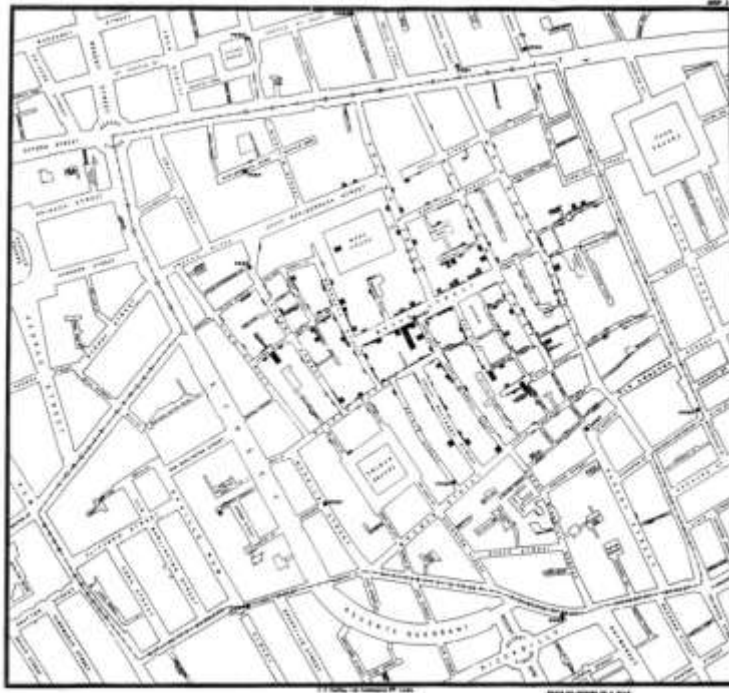
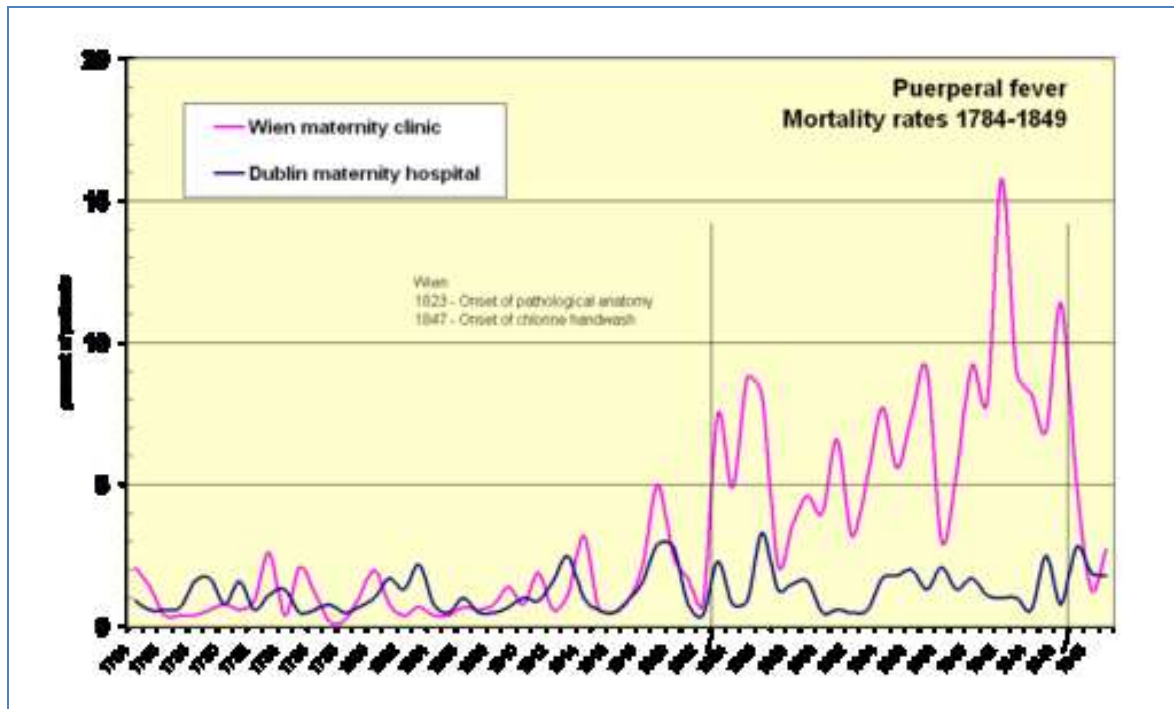


Figure 2

John Snow's original map showed the spread of cholera. The well is found at the crossing of Broad Street and Cambridge Street.

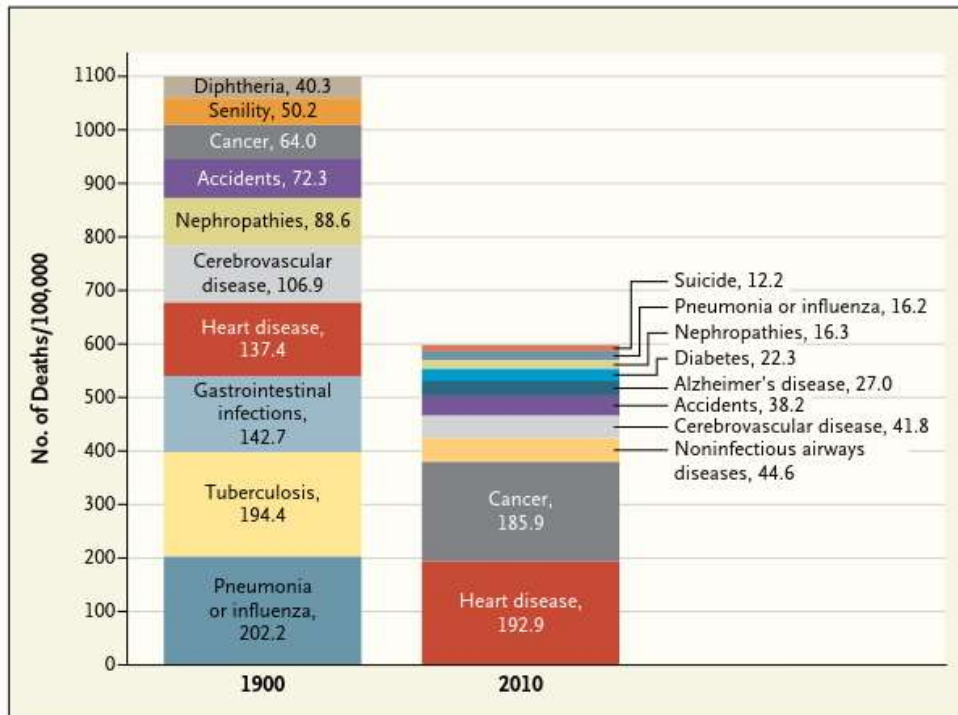


2Figure 4

Deaths caused by puerperal fever in Vienna and Dublin (Reference)

The interpretation and approach of **modern epidemiology** was greatly expanded later. Classical epidemiology dealt with the epidemics of communicable diseases almost completely. However, the cause-of-death factors have changed remarkably in developed countries in the last 80 years. Instead of communicable diseases cardiovascular and tumour diseases have become the leading cause-of-death factors, which lead to a wider and more complex interpretation of the concept of epidemiology.

It was after World War II that modern epidemiology formulated the principles of **study design** and the techniques of data collection and analysis, which helped clarify the exploration and assessment of the risk factors of chronic diseases. Such a special study method was the **case control study** (which will be introduced in detail later), which provides retrospective possibilities: it seeks the presence or absence of risk factors examining ill and non-ill (healthy) groups. **Cohort studies** or **prospective studies** are based on an exposed and a non-exposed group, where, however, the members of both groups are healthy. In the study they want to see in which proportion a given disease develops in each group.



Top 10 Causes of Death: 1900 vs. 2010.

Data are from the Centers for Disease Control and Prevention.

3Figure 5

Leading causes of death in the United States of America (Jones, 2012)

The classic study by **Doll** and **Hill** to clarify the connection between smoking and lung cancer (1950) was one of the first case control studies ever. Doll and Hill examined the smoking habits and other factors affecting the health status of 700 men and women with lung cancer. The control group had a similar number of patients hospitalized for non-tumour diseases. As a result of the study the role of smoking in developing lung cancer was clarified.

BRITISH MEDICAL JOURNAL

LONDON SATURDAY SEPTEMBER 30 1950

SMOKING AND CARCINOMA OF THE LUNG

PRELIMINARY REPORT

BY

RICHARD DOLL, M.D., M.R.C.P.

Member of the Statistical Research Unit of the Medical Research Council

AND

A. BRADFORD HILL, Ph.D., D.Sc.

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Figure 6

The title page of Doll and Hill's publication of 1950

A classic example of cohort studies is the *Framingham (Heart) Study*, started in 1948, in which 5 209 male and female citizens of Framingham (Massachusetts, U.S.A.) aged 30-62 were examined in order to clarify the risk factors of coronary disease. The people involved, who were all healthy at the beginning of the study, were placed in two groups according to whether they were exposed or non-exposed to risk factors. Then the evolution of the disease was examined in the two groups. The study began with a medical examination and the administration of a questionnaire on lifestyle, which was repeated every two years complemented by laboratory examinations. Later, in 1971, the study was expanded to include another 5 124 people who were the relatives of the original participants (their adult children and their spouses).

In the Framingham study the most important risk factors of cardiovascular diseases, i.e. high blood pressure, high blood lipid levels, smoking, obesity, diabetes and lack of exercise, were successfully identified. The most important findings of the study:

(1960). Smoking increases the risk of cardiac diseases.

(1961). Cholesterol levels, blood pressure and ECG deviations are related to the risk of cardiac diseases.

1967. Physical activity lowers, while obesity increases the risk of cardiac disease.

1970. High blood pressure increases the risk of a stroke.

1976. Menopause increases the risk of cardiac disease.

1978. Psychosocial factors influence the occurrence of cardiac diseases.

1988. High HDL cholesterol levels lower the risk of death.

1994. The enlargement of the left cardiac chamber increases the risk of stroke.

1996. The advancement of hypertension leads to heart failure.

2.2. THE DEFINITIONS OF HEALTH AND ILLNESS

Concerning the topic of epidemiology, first of all, it is important to define the concepts of health and illness by drawing the dividing line between the two. Below are some of the definitions for health and illness which people have come up with.

The classical author, Hippocrates, described health as the **harmony of the individual's complete balance**. He ascribed appropriate daily routine and lifestyle of great importance in attaining it.

Galen summarized the factors comprising health in a way, which is practically still valid today, by discussing '*res naturales*' (the physiological operation of the organism) '*res non-naturales*' (processes independent of the organism) and '*res contra naturam*' (the causes of diseases):

- light and air
- exercise and calm
- sleep and being awake
- processes of development and deterioration
- the harmony and control of passion.

According to **Blohmke** our present perspective is based on the assumption that man is a bio-social creature and health is the dynamic status of balance between the living organism and its internal and external environment. Consequently, our definition reads:

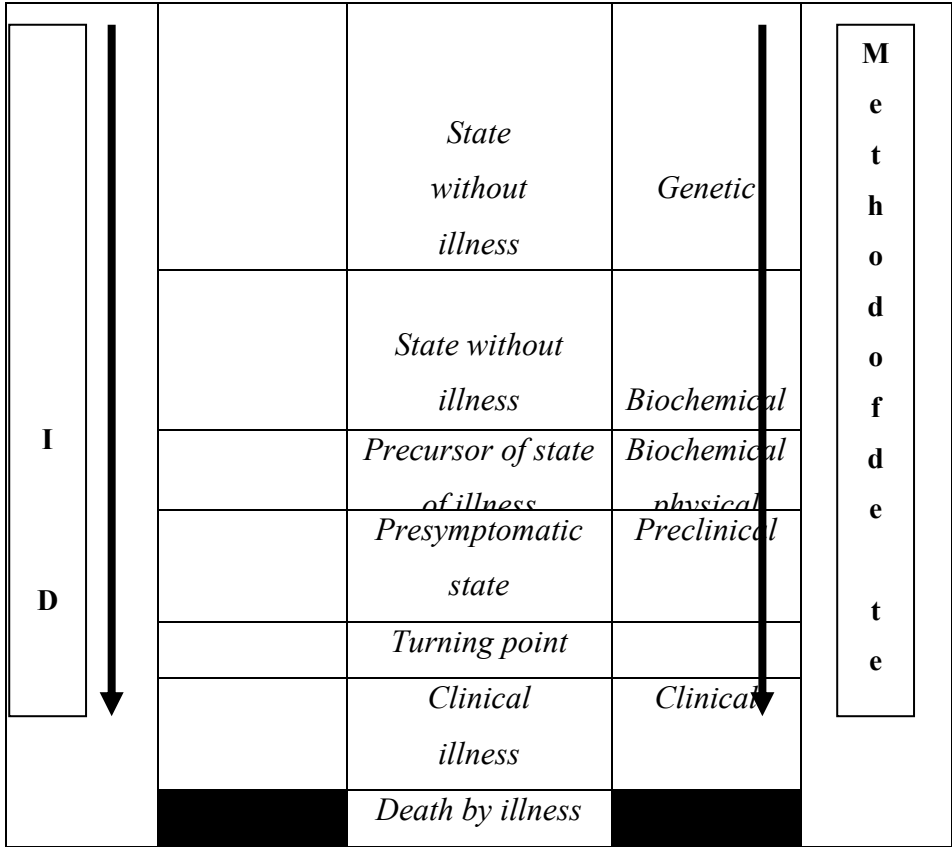
Health is a status of operation of the living organism, which, on the one hand, ensures the balanced and undisturbed operation of the organs, and, on the other hand, allows the living being to adapt to its environment. The changing of health is a balanced dynamic status, which evolves differently in every situation for every organism.

Consequently, illness is a disturbance between the dynamic interaction of the organism and its environment that cannot be compensated for due to a failure of the ability of adaptation, and thus the harmonious operation is compromised. The bio-social model of the evolution of

illness shows well the points where psychosocial factors influence the harmonious operation of the organism via the neuroendocrine system.

In his illness spectrum Bothwell summarised the stages, dynamics and possibilities of detection of illness.

Birth



Death

Figure 7
Bothwell's spectrum of illness

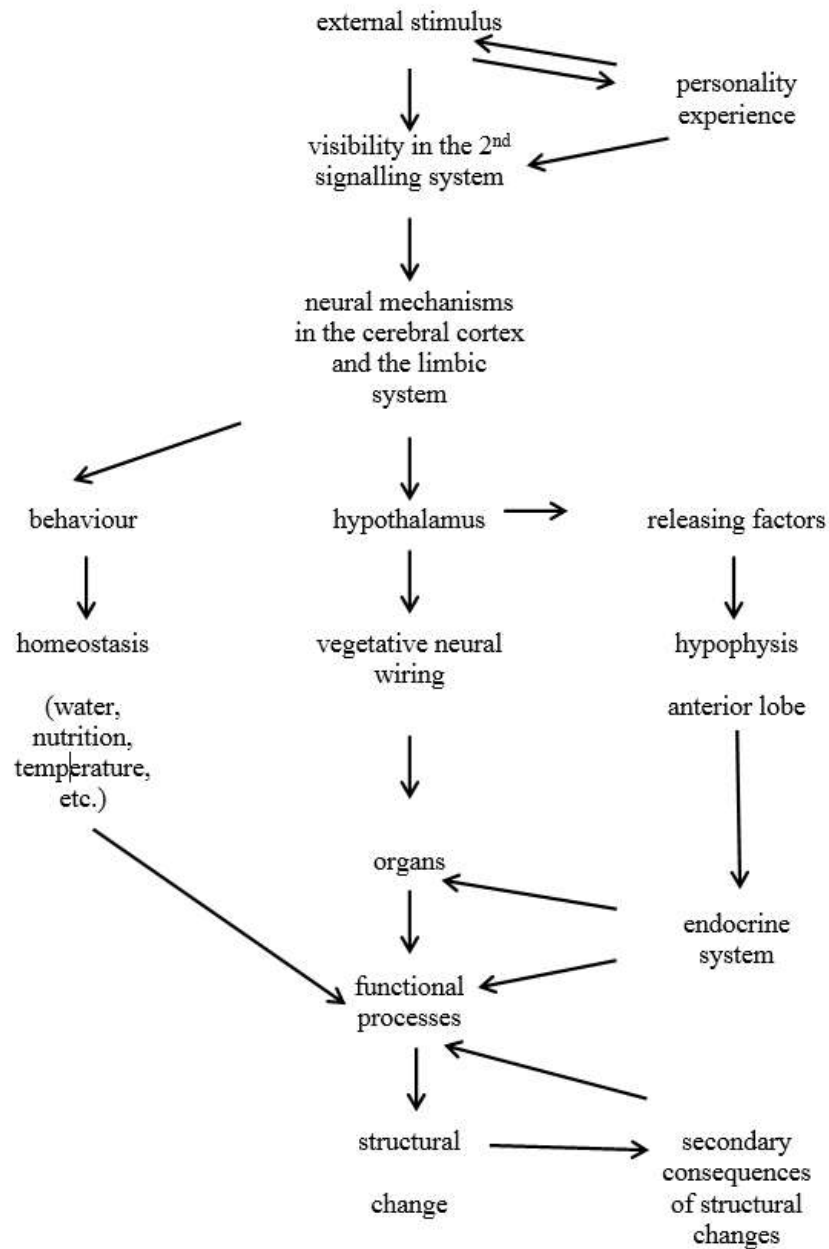


Figure 8

The bio-social model of the evolution of illness

The World Health Organization (WHO) has also created its definition:

“Health is the state of complete physical, mental and social wealth, and not only the absence of illness and disability.”

The definition above was completed by the WHO at the World Conference in Almaty by defining the right for health as a basic human right.

By the successive layers of the concentrically expanding image of the environment Dahlgren and Whitehead's model emphasises the influence of external effects by individual factors that determine health.

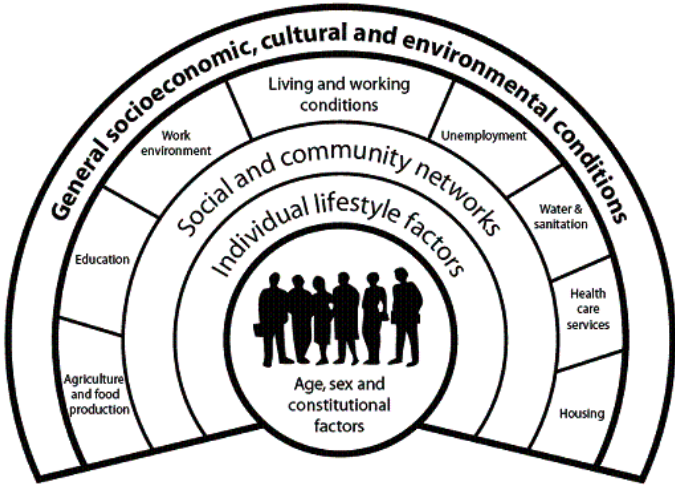
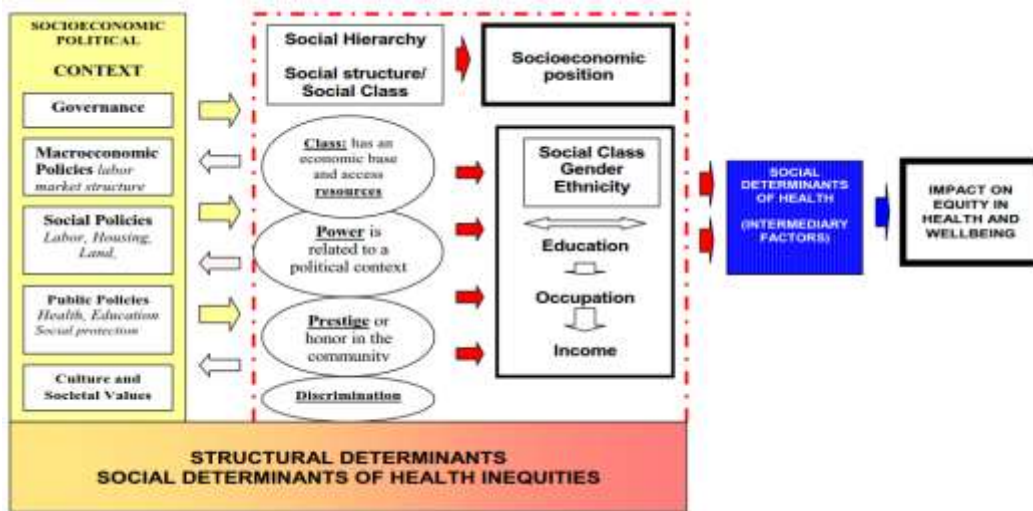


Figure 9

Dahlgren and Whitehead's layered health model (Dahlgren, Whitehead, 1991)

The World Health Organisation created the Commission on Social Determinants of Health, in which the experts have reviewed the theories and health models related to the deterioration of health and evolution of illness. The WHO organisation developed a detailed model, which summarises the individual and social factors and the interactions among them which determine health that could be identified on the basis of the literature.



4Figure 10

The structural and intermediate factors and their interactions that determine health (WHO, 1997)

All in all, health is a rather complicated state of balance, which is a result of various interactions, and its maintenance is the result of continuous and conscious activities.

2.3. THE CONCEPT, SCOPE AND METHODOLOGICAL BRANCHES OF EPIDEMIOLOGY

Epidemiology studies the factors that determine the **incidence, distribution and origins** of illnesses at the level of a population.

It extensively examines the phenomena and events related to health status, also including the risk factors affecting the evolution of illnesses and morbidity and mortality data. In a wider sense it also includes the public health measures taken in connection with illnesses and the assessment of the effectiveness of healthcare.

Literally the word *epidemiology* means science dealing with the phenomena occurring among the people. Until the middle of the 20th century it mostly dealt with communicable diseases, since they presented the greatest threat to the population. Today, however, due to the changes in the leading causes of death, it primarily studies chronic, non-communicable illnesses.

From a methodological perspective epidemiology is divided into three main branches.

Descriptive epidemiology studies the distribution of illnesses, with special attention given to which population or sub-population it affects (e.g. according to age, sex, occupation), in which geographical locations the highest and the lowest the incidence of the given illness is and how its incidence has changed over time. On the basis of that information an epidemiological hypothesis about the nature of the disease can be created.

Analytical epidemiology investigates the causal factors of the development of diseases. It looks for relationships between the incidence of the illnesses studied and their assumed causes (e.g. the connection of lung cancer and smoking), and while doing so it tests the hypotheses of descriptive analyses in order to decide whether the factor considered to be a given causal factor does really cause (or prevent) the disease. The identification of risk factors usually belongs to the analytical methods.

Intervention (experimental) epidemiology applies experimental methods for confirming the results of analytical epidemiology. The interventions are carried out among human populations under close ethical control. Intervention studies strive to verify causal relationships between assumed aetiological factors and the occurrence of diseases. Such an

intervention at population level is the addition of iodine to common salt in order to prevent goitre.

Of course, in everyday practice the above-mentioned branches of epidemiology do not strictly occur separately; in many cases the elements of several methods are used simultaneously. The examination-analysis aspects belonging to the particular methods are discussed in detail in later chapters. The major types of epidemiological studies are illustrated by the figure below.

diagnostic	<ul style="list-style-type: none"> classic (test characteristics) modern (dg functions) 	
etiological	<ul style="list-style-type: none"> descriptive <ul style="list-style-type: none"> case, case series analysis of aggregate data population correlation cross-sectional analytic <ul style="list-style-type: none"> cohort case control 	
prognostic	<ul style="list-style-type: none"> descriptive intervention <ul style="list-style-type: none"> experimental non-experimental 	

Figure 11

Types of epidemiological studies (Vokó, 2011)

2.4. BASIC CONCEPTS

In order to fulfil the requirements according to the definition of epidemiology (incidence, distribution and cause of diseases), first one has to determine the indices necessary for establishing the incidence of diseases. Now, let us present how the indices are calculated and what their strengths and the limitations of their use are.

2.4.1. Frequency

The simplest way of acquiring information about a given disease is when one counts the number of people suffering from it. Nevertheless, however important these data are, they do not provide much valuable information for those dealing with public health. It is also vital to know in how large population the given number of the patients occur.

Example:

<i>Location</i>	<i>Number of new hepatitis cases</i>	<i>Period studied</i>	<i>Population</i>
Town 'A'	58	1995	25 000
Town 'B'	35	1994-95	7 000

At first sight it seems that hepatitis is a lot more common in town 'a' than in town 'B'. However, town 'A' reported the data from one year only, while town 'B' those of two years. After further calculation one arrives at different conclusions according to the reasoning below.

Step 1: Calculating the number of patients for one year:

town 'A': 58 patients/1 year

tow 'B': 17.5 patients/1 year

Step 2: Calculating the number of patients for 10⁵ people

town 'A': 58 patients/year \Rightarrow for 25 000 inhabitants (100 000/25 000)

232 patients/year/10⁵

town 'B': 17.5 patients/year \Rightarrow for 7 000 inhabitants (100 000/7 000)

250 patients/year/10⁵

Having the calculations done, it becomes visible that the incidence of hepatitis is nearly the same in the two towns. In order to be able to measure and interpret the incidence of diseases correctly several indices have to be used appropriately.

2.4.2. Risk factors and exposure

As mentioned earlier one of the purposes of epidemiological studies is to discover the causal factors of the appearance of diseases. In the case of a considerable number of chronic diseases it is not possible to detect the direct causes; researchers have to content themselves with seeking factors in whose presence the disease studied occurs more often, while in their absence more rarely. These factors that help the development of diseases are the **risk factors**, which can be grouped as follows according to their characteristics:

- environmental factors (air, water, soil, noise, etc.)
- lifestyle factors (nutrition, physical activity, smoking, alcohol consumption, etc.)
- social factors (socio-economic status, income, occupation, etc.)
- genetic factors (not only in the case of hereditary diseases!)

Exposure means that the risk factor studied is present in the person examined. It does not, however, necessarily mean that it causes illness in everybody. It is extremely important to know the length and dose of exposure (e.g. how long he/she has been smoking, the amount of cigarettes smoked, or how long someone has worked under radiation and what the approximate dose is).

2.4.3. Incidence

Incidence compares the number of new patients observed in a given period to the average number of the population during the period exposed to the risk (population at risk). A member of the population at risk is every person who at the beginning of the period studied is still free of the given disease but theoretically might become a patient later, i.e. he/she becomes a case.

In epidemiological studies to kinds of incidence calculations can be done.

The first one is **cumulative incidence**, whose calculation normally refers to one year. The mode of its calculation: the number of new patients observed during the given period divided by the number of the population exposed to the risk at the beginning of the period. In the formulas the index 'k' represents the reference population (e.g. 1000, 10 000 inhabitants).

$$I = \frac{\text{number of new cases during given period}}{\text{number of population at risk}} \times k$$

Establishing the number of people affected by the disease is not always simple. Depending on how one defines the range of people exposed to the risk in the denominator, calculations produce different results. For cumulative incidence the entire population is observed from the beginning to the end of the studied period. In practice, however, some participants are not involved in the study from the beginning (they join later) and/or quit before the end (they die or move away). As a consequence, in a five-year study the **follow-up** period may vary greatly in the case of the individual participants.

Another kind of index is the so-called **person-year incidence**, which takes the above phenomenon into account in incidence calculation. This means that in the denominator all the person-time, i.e. the **total person-time** is included. Total person-time means how much time the people in the study spent exposed to the effect of the risk factor altogether. The example below shows the calculation of person-year incidence (Table 3).

$$\text{PVI} = \frac{\text{number of new patients during observation}}{\text{total person-year during observation}} \times k$$

Example:

Table 3

2.4.3. Person-year incidence calculation

	1986	1986	1987	1987	1988	1988	1989	1989	1990	1990	1991	Total time	
	Jan	July	Jan	July	Jan	July	Jan	July	Jan	July	Jan	at risk	
Person A	●—————											5.0	
Person B		●—————◆											3.0
Person C	●—————											2.0	
Person D			●—————									4.0	
Person E					●—————◆						2.5		
												16.5	

During the 5-year period studied the disease developed in two cases of the 5 people observed. Thus, the incidence of the disease: 2 patients/5 persons= 0.4, i.e. 40%. However, from the table it is noticed that it was only person ‘A’ who participated in the study throughout the five years. The others could only be observed during the time in the last column. Thus, applying the formula of person-year incidence (incidence density): 2 cases/16.5 person-year = 12.1 cases/ 100 person-year.

The term person-year incidence is used in the Hungarian literature. The international literature calls the method incidence density.

Some limitations in its application also need to be mentioned. In order to prevent systematic distortions during the whole study it is necessary to calculate incidence for the particular parts of periods too. It is important to analyse whether those quitting or dropping out of the observation form a well-definable group.

The definition of the exact number of the population exposed to the risk, or risk population, in the denominator it is also of utmost importance. If, for instance, the incidence of endometriosis cancer was sought, the number of men is automatically eliminated from the population. Another factor is that the number of women undergoing hysterectomy increases

with age within the given age group, and due to the absence of a womb no endometrium tumour can develop in them. Thus, they are not included in the population at risk either.

2.4.4. Prevalence

In **point prevalence** calculation the number of patients at a given point of time is compared to the number of inhabitants. Thus, one always has to talk about a particular patient number at a given point of time (e.g. 1 January or 31 December). In the formulas the index 'k' represents the reference population (e.g. 1000, 10 000 inhabitants).

$$P_0 = \frac{\text{number of cases at a given time}}{\text{number of population at risk}} \times k$$

Period prevalence measures the number of patients during a given period (e.g. one year, two months). In the formulas the index 'k' represents the reference population (e.g. 1000, 10 000 inhabitants).

$$P_t = \frac{\text{number of patients at the beginning of period} + \text{number of new patients}}{\text{number of population at risk}} \times k$$

From the formulas so far it follows that between period prevalence, point prevalence and incidence there is the following relationship:

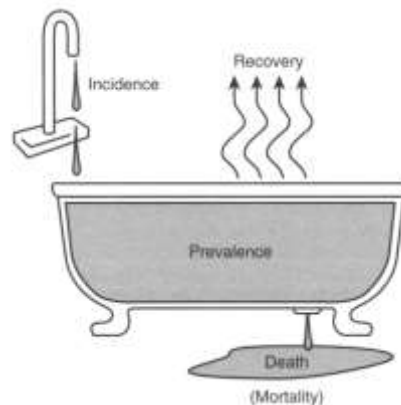
$$P_t = P_0 + I$$

Lifetime prevalence expresses the probability of developing the disease during the lifetime of the persons studied.

The figure below illustrates the relationship of prevalence and incidence. The water pouring from the tap represents (the number of new patients) incidence, while the water in the

container (the total patient number) prevalence. The water leaking or evaporating from the container indicates decrease in the prevalence, which may be due to either healing or death. Between prevalence (P), incidence (I) and the average duration of the disease (T) there is the relationship below:

$$P = I \times T$$



5Figure 12

The relationship of incidence and prevalence

2.4.5. Morbidity and mortality indices

While using incidence and prevalence various data may be substituted in the numerator and denominator as well. Thus, special indices of remarkable importance to epidemiology can be obtained.

Among the special types of **incidence** the most frequently used indices are morbidity, mortality and lethality.

number of people falling ill with examined disease during given period

$$\text{Morbidity} = \frac{\text{number of people falling ill with examined disease during given period}}{\text{number of population}}$$

number of deaths caused by examined disease during given period

$$\text{Mortality} = \frac{\text{number of deaths caused by examined disease during given period}}{\text{number of population}}$$

number of deaths caused by examined disease

$$\text{Lethality} = \frac{\text{number of deaths caused by examined disease}}{\text{number of people suffering from examined disease}}$$

Among the special types of **prevalence** (which are very often mistaken for incidence) the ratio of development disorders needs to be highlighted.

$$\text{Congenital development disorders} = \frac{\text{number of people born with given development disorder}}{\text{live births}}$$

The interpretation of perinatal death, which means the number of those dying in late foetal age or in the first week, is interesting. Practically, it may be identified with the concept of period prevalence: the total number of those dying in late foetal age or stillborn (point prevalence) and those dying in the first week (incidence) is compared to the total number of new-borns (born alive or dead).

The various epidemiological indices are calculated in different ways. By changing the numerators and denominators in the above-mentioned basic and specific incidence, prevalence and other indices one obtains different results.

Crude rates are values calculated for the entire population. In the case of determining the mortality rate, one gets the result below in the following example of deaths caused by tumour. That means that there are 183.8 deaths per 100 000 inhabitants per year.

$$\text{Mortality}_{\text{crude, 1980}} = \frac{416,481 \text{ deaths}}{226,546,000 \text{ inhabitants}} = 183.8 / 10^5 / \text{year}$$

The **age-specific** mortality rate, which is the most commonly used category-specific index, shows the mortality rates *within a given age group*. Here the deaths occurring in the given age group is divided by the number of people in the age group.

$$\text{Mortality}_{\text{aged 35-39, 1980}} = \frac{4,684 \text{ deaths}}{13,965,000 \text{ inhabitants}} = 33.5 / 10^5 / \text{year}$$

4 table

Crude and age-specific tumour-related mortality rates

Example:

<i>Age</i>	<i>Number of tumour cases</i>	<i>Population</i>	<i>Mortality rate per 100,000 residents</i>
below 5 years age	686	16 348 000	4.2
5 - 9	777	16 700 000	4.7
10 - 14	720	18 242 000	3.9
15 - 19	1145	21 168 000	5.4
20 - 24	1538	21 319 000	7.2
25 - 29	2041	19 521 000	10.5
30 - 34	3040	17 561 000	17.3
35 - 39	4684	13 965 000	33.5
40 - 44	7786	11 669 000	66.7
45 - 49	14 230	11 090 000	128.3
50 - 54	26 800	11 710 000	228.9
55 - 59	41 600	11 615 000	358.2
60 - 64	53 045	10 088 000	525.8
65 - 74	127 430	15 581 000	817.9
75 +	130 959	9 969 000	1313.7
Total:	416 481	226 546 000	183.8

In the United States of America (1980)

2.5. SOURCES OF DATA IN EPIDEMIOLOGY

The sources of data are key elements in epidemiological examinations and studies, since correct conclusions can only be drawn from appropriately gathered data. Incorrect or improperly systematized data, apart from impreciseness, are also dangerous because they suggest false conclusions and incorrect causal relationships.

This chapter discusses the sources of epidemiological data, presenting classical data sources as well as modern data.

2.5.1. Demographic data

In collecting, analysing and publishing demographic data the Hungarian Central Statistical Office (KSH) plays an important role. The most comprehensive summary of these data is the census, taken every ten years, which besides the number of population also collects data concerning the social and physical environment. Census data are recorded in county yearbooks, which provide data broken down into settlements.

The County Directorates of KSH - apart from national publications - also publish yearbooks on population and demographic data (e.g. live births, deaths, etc.).

These routinely collected and published data are of fundamental importance from the perspective of epidemiological analyses, but they also have their limitations:

- the number of deaths according to groups of causes of death for the whole county are not provided broken down by gender.
- demographic yearbooks provide mortality rates by causes of death only per 1 000 inhabitants, which is not useful information from an epidemiological perspective (it needs standardization!).
- the groups of causes of deaths published in the county yearbooks and the demographic yearbook are not unified; it would be advisable to use BNO codes in county yearbooks too

2.5.2. Morbidity statistics

Information about morbidity, i.e. illnesses and pathological states, usually come from the healthcare system, where patients and carers interact. That means that routine morbidity statistics are based on data recorded there. This part of the population's morbidity known by

the healthcare system is called **known** or recorded **morbidity**. Illnesses which affect the health status of the population but are not detected are called *hidden morbidity*.

The sources of data concerning known morbidity are the following.

2.5.2.1. Compulsory reporting and surveillance

The **unified obligation of reporting** serves the monitoring of the occurrence and changes of the diseases in this category. The institutions obliged to report the necessary data report them, while the registry totalizes the data thus collected and publishes the results regularly. This way a two-way communication takes place between the reporter and the collector of the data.

Surveillance is a wider, continuous analysing activity encompassing every important aspect of the occurrence and the spread of the given disease, and its purpose is the prevention of the given disease in the population in the sphere of operation of surveillance (settlement, region, country). Surveillance was first applied with communicable diseases, but today it is applied to a wide range of diseases in the developed countries: monitoring malignant tumours, congenital developmental disorders, side effects of medicines, nutritional problems, adverse environmental effects and occupational diseases.

The special information system of surveillance is registration.

2.5.2.2. Registries

In several respects registries represent additional information compared to surveillance. Registries are continuous, coherent documentation systems, which - after diagnosing the disease within the area of registration - involve:

- the immediate registration of the patient
- double-checking to avoid repeated registration
- continuous monitoring of every event related to the patient until his/her death or removal from the registry or leaving the area of registration
- the continuous maintenance of the registry.

Another important characteristic of population-based registries is that the registration area determines the population from which the patients may come from. As a result, the information about the population together with the registry data allow incidence measurements and analyses from the perspectives of both the etiological and temporal changes (trends).

The most important registries are the following:

- cancer registries
- twin registries
- the congenital disorder registry.

2.5.2.3. Statistics of healthcare institutions

Healthcare institutions keep records of their patients. Although in various forms, but such registries are found in GP's surgeries, outpatient clinics, inpatient institutions, care homes, etc. By themselves they are not suitable for morbidity investigations since the populations, from which the patients come from, are unknown.

Since the 1980s, thanks to the dramatic development and spread of hospital IT systems, more and more countries have introduced compulsory provision of data concerning the entire number of patients. Concerning the individual patients hospitals have different information available, but according to an international agreement there is a **Minimum Basic Data Set** (MBDS) about every patient, which is the same in all participating countries. The provision of MBDS has been compulsory in Hungary in an electronically recorded form since 1992.

In Hungary institutions providing healthcare are funded on the basis of data supplied by them. The collection and storage of these data was started by the Healthcare Information Centre of the Ministry of Health (GYÓGYINFÓK, Szekszárd); today it is carried out by the Department of Finance and Information Technology of the National Health Insurance Fund of Hungary.

2.5.2.4. Social security statistics

The importance of social security statistics is ever increasing today. They include records on temporal (sick leave) and permanent (permanent disability) incapacity.

Sick leave statistics provide an insight into the morbidity causing the incapacity of those entitled to sick leaves. Nevertheless, they do not provide a sufficient picture of the whole population. In analyses important aspects may be: the cases and days of sick leave, the average number of days per case, the amount of the average payment per day, the number of people on sick leave per day, etc. However, several factors can also distort these data. White-collar workers might not turn to a doctor with a certain disease that prompts a blue-collar worker to ask for sick leave, meaning a higher number of people on sick leave among physical workers. Unemployment also influences the number of sick leave cases.

Permanent disability statistics provide an insight into morbidity causing permanent incapacity among the insured. The limitations of its applicability are similar to that of sick leave statistics.

2.5.3. Hidden morbidity

All the illnesses, diseases and states with which people do not turn to any level of the healthcare system remain hidden to it (or are not detected or are not recorded or reported) and comprise hidden morbidity. Targeted morbidity investigations are meant to explore hidden morbidity.

In these it is not the members of the population that turn to the healthcare system with their complaints but active detection takes place, i.e. the person carrying out the investigation initiates the examination of the people in the target population. The study is usually limited to a sample representing the population and conclusions about the entire population are drawn from the results of this sample.

The goal of morbidity investigations is to acquire more comprehensive information about the health status of the target population, the incidence, the prevalence, healthcare needs, the use of healthcare and the risk factors than that in the registries.

In hidden morbidity studies the most common epidemiological methods are screening and prospective studies.

2.5.3.1. Screening

The objective of secondary screenings is the presumptive detection of hidden diseases and deteriorations without any clinical symptoms. For that end, tests that are easy and quick to perform and are acceptable to the people screened without any risks are used.

The most important role of screening is the recognition of pathological states and illnesses in time. Timely detection, however, is not enough by itself because patients' chances of survival only improve if, besides the diagnosis, treatment is also started earlier. Thus, the early recognition of clinical pictures remains only an illusory advantage in the absence of effective early treatment, since the patient's survival chances do not improve due to the lack of early treatment. An early diagnosis only becomes a real advantage if the patient's survival improves compared to the unscreened population as a result of treatment started early.

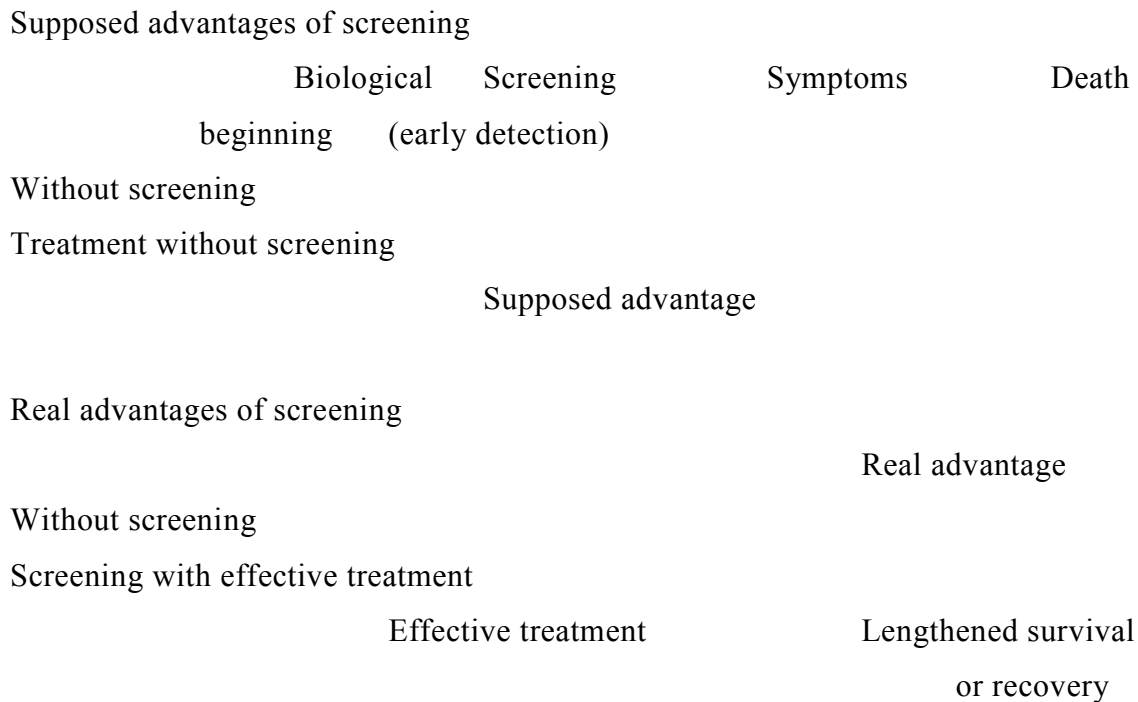


Figure 13

The relationship between early screening and the chances of survival

The working group of the WHO summarized the conditions (Wilson-Junger criteria) for successful screening in 1968

- the target disease is important for public health regarding incidence and mortality
- the origins and course of the disease are known and can be influenced by rational intervention
- the strategy of the screening is known
- a simple, cheap, socially accepted method suitable for the screening is available
- the conditions for diagnosing and treating the target disease detected by screening are available
- cost-effective screening method

Screening tests must fulfil the following special epidemiological requirements:

- | |
|--|
| <ul style="list-style-type: none"> ▪ reproductivity ▪ validity ▪ specificity ▪ sensitivity ▪ predictivity |
|--|

Reproductivity (reproducibility) is the basis of the reliability of a screening test. A screening test is considered reliable if several repetitions with the same individual under identical circumstances produce the same results. **Reproductivity** is influenced by numerous factors, which may modify the results. Biological fluctuations in the individual may cause differences in measuring blood pressure, for example. The lack of authenticity of measuring instruments may also deceive the researcher. A proven practice to decrease variation due to the observer's inconsistency is when two independent persons carry out the measurement or the assessment.

Validity concerns the ability of the test to screen and it measures how the given screening test fulfils the task it was designed for. In other words, whether it is able to separate the positive and negative cases in the population screened.

Validity measures the ability to screen by sensitivity and specificity. In order to be able to interpret the sensitivity and specificity of a screening test, the results of the screening test need to be compared to a reference diagnostic test to determine whether the screening test measured the presence or absence of the disease correctly. The results obtained are shown in the chart below.

Figure 14

Testing the screening ability of a screening test

	the actual state of the patient by reference diagnostic test		
	<i>positive</i> <i>(ill)</i>	<i>negative</i> <i>(healthy)</i>	
screening test results			
<i>positive (+)</i>	a (genuine positive)	b (false positive)	<i>a + b</i> <i>(total of positive)</i>

<i>negative (-)</i>	c (false negative)	d (genuine negative)	<i>c + d</i> <i>(total of negative)</i>
	<i>a + c</i> <i>(total of ill)</i>	<i>b + d</i> <i>(total of healthy)</i>	<i>a + b + c + d</i>

a The number of positive (pathological) results measured among ill people.

Genuine positive:

The number of ill people detected by the screening test

b The number of positive (pathological) results measured among healthy people.

False positive:

The number of non-ill people detected by the screening test.

c The number of negative results measured among ill people.

False negative:

Ill people not identified by the screening test.

d The number of negative results measured among healthy people.

Genuine negative:

The number of negative, non-ill people according to the screening test.

The formula of validity based on the above:

$$\text{Validity} = \frac{a + d}{a + b + c + d}$$

Sensitivity refers to the ability of a test to give a positive result if the individual tested is really ill, i.e. it identifies genuinely positive results. By increasing the sensitivity of a screening test the number of false negative results is decreased.

$$\text{Sensitivity} = \frac{a}{a + c}$$

$$a + b + c + d$$

Specificity is the ability of screening tests to identify the real negative individuals, i.e. it gives a negative result if the individual tested is not ill. By increasing specificity the number of false positive results decreases.

$$\text{Specificity} = \frac{d}{b + d}$$

Pre- screening programmes are **applied practically** on large populations it is important to analyse the sensitivity and specificity thoroughly and to verify the determination of the decision level in clinical practice. The WHO has developed international recommendations, standards, in connection with numerous diseases (e.g. diabetes, hypertonia, high cholesterol level) for determining the levels of pathological values.

The effectiveness of screening tests may be increased by the **combined** application of various tests. As it is shown in figure 12, first a high sensitivity test is used, by which the genuinely positive ill people will be positive, and a number of false positive test results will also be obtained. In the second stage a high specificity screening test is used to eliminate the false positive results of the first test. Even the combination of screening tests cannot substitute the clinical examination and diagnosis of the cases also proved positive after the second stage.

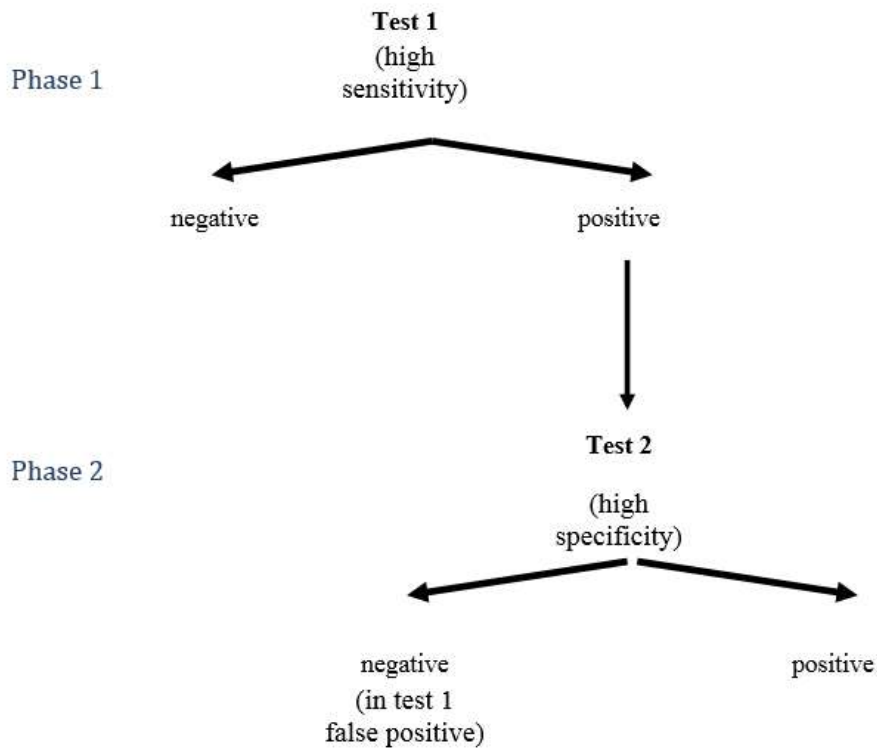


Figure 15

Combination of screening tests

A further characteristic of screening tests is positive and negative predication.

The **positive predictive value** of a given screening test shows the probability of a person with a positive result to be ill.

$$\text{Positive predictive value} = \frac{a}{a + b}$$

And the **negative predictive value** indicates the probability of a person with a negative screening result to be actually free of the given disease.

$$\text{Negative predictive value} = \frac{d}{c + d}$$

The application of screening tests is widespread in the practice of hospitals and includes numerous groups of diseases. Some selected examples: goitre, Rh- and OAB incompatibility among pregnant women, phenylketonuria among newborns and dichromacy at drivers' medical tests.

2.5.3.2. Follow-up studies

In epidemiology following the events related to the health statuses and regular observation of individuals in a target population is called prospective study.

The target population mentioned in the definition seldom means an entire population, representative samples are rather investigated.

Observation may be carried out in several ways. Mostly they take place in the observed person's own environment by oral interview (in personal or by telephone) and by filling in questionnaires. Another common form of data collection is the self-interviewing (diary, questionnaires sent by mail).

The **frequency** of data recording may differ depending on the type of study. For general morbidity studies, for example, data are recorded for a year every two weeks or once a month. Of course, the rarer the observations happen, the less precise the data obtained are, since individuals' memories fade.

A major **problem** in prospective studies is when the people selected for the representative sample do not actually agree to participate and/or a considerable part of the participants drop out. A drop-out rate of 15% may already cause serious distortions in the result of the study. It is reasonable to analyse drop-outs separately to see if they have a common demographic-epidemiological characteristic.

2.6. TYPES OF EPIDEMIOLOGICAL STUDIES

The goal of this chapter is to introduce the most important types of epidemiological studies, their applications, limitations and the fundamental differences between the individual methods. The table shows the classification of epidemiological studies.

4Table 4

Major types of epidemiological studies

<i>Study</i>	<i>Type</i>
Descriptive studies	Individual studies
	Case report and case series
	Cross-sectional study
	Population (correlation or ecological) studies
Analytical studies	Case-control studies
	Cohort study
Intervention studies	Randomized controlled trials
	Areal intervention studies
	General population intervention study

2.6.1. Descriptive studies

Descriptive epidemiology studies the distribution of illnesses, with special attention to which population or sub-population it affects (**personal characteristics:** age, sex, occupation), in which geographical **locations** (geographical-social environment) the higher and the lower the incidence of the given illness is and how its incidence has changed **over time**. On the basis of this information an epidemiological hypothesis about the nature of the disease can be formulated. All the various types of descriptive studies examine diseases according to the three aspects above (person, location, time).

2.6.1.1. Case report and case series

Studies based on individual data may mean a report of a case or the preparation of a so-called case series including several cases.

Their significance is that on the basis of the information from the descriptions hypotheses, which can only be verified by stronger epidemiological studies, may be generated via the problem

A classic example of case reports is the description of the connection of oral anticoncipients (contraceptive pills) and pulmonary embolism. In 1961 a case report in which a 40-year old premenopausal woman received oral anticoncipients treatment for endometriosis was published. Five weeks after the beginning of the treatment she developed pulmonary embolism. Considering that pulmonary embolism is much more common in much older postmenopausal women, the observer assumed that the medication had been responsible for the problem.

As an example for **case series** the first description of AIDS may be used. Within six months in 1980-1981 five earlier healthy homosexual young men were diagnosed with pneumonia caused by *Pneumocystis Carinii* in three Los Angeles hospitals. The data were shocking because that type of pneumonia had been observable almost only in elderly people with suppressed immune systems earlier. The unusual circumstances indicated that it was a disease earlier unknown, which became known as Acquired Immunodeficiency Syndrome (AIDS).

After that, in 1982 in Denmark, advanced Kaposi's sarcoma and/or a fever of unknown origin was recorded in four previously healthy homosexual young men. One of the patients later died from pneumonia caused by *Pneumocystis Carinii*. Further examinations revealed that the patients' immune systems were seriously damaged. Three of the four patients had never been to the USA, where the Acquired Immunodeficiency Syndrome had been described but its presence was to be assumed also in the case of those European homosexual men, who had been admitted to hospital with a fever of unknown origin, spleen-lymph gland lesions, opportunistic infections or Kaposi's sarcoma.

The following example stresses the importance of case series too. In 1941 78 babies were born with cataracts and some others with heart developmental disorders in Australia. The cases occurred in similar forms in various areas during the same period. It made Norman McAlister Gregg curious and he suspected a causal relationship between the cases. The description of the cases disclosed that the serious rubeola epidemic raging in Australia between 1940 and 41 was to blame for the congenital disorders, since they occurred as a consequence of infections suffered in early pregnancy. The mothers of 68 of the 78 children born with cataracts had had infections during their pregnancies. On the basis of these, in 1943

the triad of congenital disorders occurring as a consequence of the mother’s rubeola infection (deafness, cataract, heart failure) was described.

Of course, in such cases every other factor that is or may be related to the disease must be carefully investigated. And for the verification of the assumptions suitable further examinations need to be performed too.

2.6.1.2. Cross-sectional study

The third type of descriptive epidemiological studies is the **cross-sectional survey** or **prevalence survey**, in which the presence of the risk factors and the disease are simultaneously examined in every individual participating in the study, and through them in the population, at a given time.

In a cross-sectional study the **presence or absence of the given disease and the risk factor(s)** is investigated in every member of the target population. Since the survey is limited to a given time, it cannot be determined whether the given risk factor is actually the cause or the consequence of the disease. It only shows whether the risk factor was present at the given point of time or not. In other words, it is a point prevalence study, in fact.

During the study the results are recorded in a so-called 2x2 contingency table, and then on the basis of the table the **point-prevalence of the disease** and/or **risk factor** is calculated.

5Table 5

Cross-sectional study contingency table

		D		Total:
		Yes	No	
E X P O S E D	Yes	<i>a</i>	<i>b</i>	a + b
	No	<i>c</i>	<i>d</i>	c + d
Total:		a + c	b + d	N = a+b+c+d

The point prevalence of the **disease** investigated (P_B):

in the exposed population:

$$P_{\text{in exposed population}} = \frac{a}{a + b} \times k$$

in the non-exposed population:

$$P_{\text{in non-exposed population}} = \frac{c}{c + d} \times k$$

in the entire population:

$$P_{\text{in entire population}} = \frac{a + c}{N} \times k$$

The point prevalence of the **risk factor** investigated (P_K):

among the ill:

$$P_{K \text{ among the ill}} = \frac{a}{a + c} \times k$$

among the non-ill:

$$P_{K \text{ among the non-ill}} = \frac{b}{b + d} \times k$$

among the entire population:

$$P_{K \text{ among the entire population}} = \frac{a + b}{N} \times k$$

A cross-sectional study can be categorised as an analytical epidemiological study in one special case. If the exposure studied does not change over time (e.g. blood group) or the lethality of the disease is not great, it may be considered a population-level case-control study. In other cases it would not be lucky to classify cross-sectional studies as analytical studies. It is especially true if one considers that they are not suitable for incidence measurements. Thus, they cannot be used for testing etiological hypotheses.

Prospective cohort studies are practically always preceded by cross-sectional studies to select the sub-population free of the disease and to create the exposed and non-exposed groups.

A classic example for cross-sectional studies is the systematic data collection carried out under the **National Health Survey Act** in the United States of America. In that survey, data are periodically collected on the prevalence of acute and chronic diseases, the physically disabled and the utilisation of healthcare. It involves personal interviews about households (*Health Interview Survey*) as well as standard physical examinations and laboratory tests (*Health Examination Survey*). Since 1971 the dietary habits of the randomly selected population are also examined (*Health and Nutrition Examination Survey*). Thus, the programme uses an even wider range of data.

2.6.1.3. Population (correlation or ecological) studies

Descriptive epidemiological methods, however, are suitable not only for studying individual cases but also analyses at population level.

The purpose of such analyses is to examine the relationships of deaths with various environmental, economic and social factors. The word ecological here refers to the investigation of environmental factors. The relationships between the phenomena studied are often shown in so-called correlation point diagrams. That is why ecological studies are also called correlation studies.

A classic example for correlation studies is the survey made in the United States in the 1960s, where the connection between deaths caused by coronary heart disease and per capita cigarette consumption was investigated in 44 states. That study contributed greatly to the formulation of the hypothesis according to which smoking causes coronary cardiac disease. The hypothesis was later verified by many analytical epidemiological studies.

The greatest **strength** of correlation (ecological) studies is that they are relatively fast and inexpensive to do. The reason for that is that already existing demographic data and/or the consumption data of given products are normally compared with incidence and mortality data or data on the utilisation of the healthcare system. Similarly, in various geographical regions **surveillance** data or data from national or international registries are compared to morbidity figures.

The main **limitation** of the applicability of such studies is that the risk factors cannot be linked to the illness in the case of one given person; the relationships can only be interpreted in the case of populations. In other words, the connection between alcohol consumption and chronic liver diseases is disclosed to no avail; individual risks cannot be judged even in the case of a close relationship at population level. If, nevertheless, it still happens and conclusions about lesions at an individual level are drawn from population data, a so-called ecological mistake is made. The opposite of that mistake, called an atomistic mistake, is made if conclusions concerning groups are reached on the basis of data from examinations at an individual level

Another limitation of correlation (ecological) studies is that one cannot control the various potential disturbing factors.

In correlation surveys the relationships between the parameters studied can be quantified by using the so-called **correlation coefficient** (r). This figure indicates the strength of the

connection between the risk factor and the illness. In other words, it shows how the change of one unit of the risk factor affects (increases or decreases) the number of the occurring cases of morbidity (deaths). In the classic example above an increase in cigarette consumption also results in a parallel increase in deaths caused by coronary cardiac disease.

The value of the correlation coefficient can vary between + 1 and- 1:

Table 6

The possible values of the correlation coefficient

coefficient value	connection strength	connection direction	example
0 ⇒ + 1	strengthens (closer)	identical	higher cigarette consumption, higher mortality caused by coronary disease
0	none		connection between shoe sizes and lung cancer
0 ⇒ - 1	strengthens (closer)	opposite	mothers' higher education, lower infant mortality

2.6.2. Analytical epidemiological studies

By applying analytical epidemiological methods the causal factors of the origins of diseases are examined. They look for relationships between the incidence of the illnesses studied and their assumed causes (e.g. the connection of lung cancer and smoking), and while doing so they test the hypotheses of descriptive analyses in order to decide whether the factor considered to be the given causal factor really causes (or prevents) the disease. The identification of risk factors usually belongs to the analytical methods.

2.6.2.1. Case-control studies

In case control studies the point of departure is a patient (case) group and a control group and it is investigated how the assumed risk factors occur in the two groups. That means, that the proportions of the occurrences of the assumed risk factors of the given disease are assessed in the patient and the control groups. The study focuses on the past, i.e. it is retrospective.

Retrospective	Past	Risk factor missing	Risk factor present	Risk factor missing	Risk factor present
		Gathering information			
	Present	case		control	

6Figure 16

The schematic structure of the case-control study

A so-called **patient (case) group** is made up of individuals suffering from the disease studied (or having the given health behavioural factor). In their selection several aspects need considering. The first and most important factor is the **precise definition of the disease**, the detailed breakdown of the disease groups. Today, for example, it is known that the difference between cervical cancer and the cancer of the body of the uterus is huge concerning risk factors, since promiscuity is a risk factor of the first one, while not of the latter, contrary to social-economic status, where high status is a risk factor of the cancer of the body of the uterus, while low status is that of cervical cancer.

An indispensable condition for defining diseases is the exact determination of the **diagnostic criteria**. For the diagnosis of various diseases criterion systems of different levels are available. These are established by professional associations, research teams or international organisations (e.g. WHO).

In the selections of the patients it is advisable to involve newly diagnosed cases in the study. Unfortunately, in the case of very rare diseases, where the case number is very low, it is not possible. Patient selection is usually based on the patients of the institution carrying out the study. An advantage of this is that information on the previous diseases of the patients is also available at the institution. However, special care should be taken since certain special risk factors may be present cumulatively in the area of the institution where the patients come from (e.g. in mining regions). Another popular aspect of selection is the territorial principle, where patients living in a given area (town, county, regions, etc.) are examined.

Control groups should be selected with similar attention. If the patient group is chosen from the patients of a given institution, the members of the control group must be selected there too. The same is true for applying other selection criteria (e.g. territorial principle).

The principle of **corresponding** patients means that the members of the control group have similar characteristics to those in the patient (case) group. The most common such characteristic is gender or age. That means that the counterpart of a 40-year-old male patient in the patient group must be a 40-year-old male in the control group. Of course,

correspondence may require a lot of work and expenses at times, since certain patients might be difficult to find a counterpart for.

Finding the right degree of adjustment is extremely important as over adjustment may also cause methodological mistakes resulting in false results. To avoid that several control groups may be used. In such a case the two control groups must be selected from two different locations: one, for example, from the patients of the hospital, while the other one may consist of the colleagues or relatives of the people in the patient (case) group.

6Table 7

Contingency table of the case control study

		<i>Group</i>		Total:
		Case	Control	
E X P O S E D	Yes	<i>a</i>	<i>b</i>	a + b
	No	<i>c</i>	<i>d</i>	c + d
Total:		a + c	b + d	N = a+b+c+d

During the analysis of the data, i.e. assessing the relationship between the disease and the assumed risk factor, the ratio of those exposed is examined in the two groups. Markings refer to the figure presenting the structure of a case control study.

The ratio of the exposed population:

in the patient (case) group:

$$E_{\text{case group}} = \frac{a}{a + c}$$

in the control group:

$$E_{\text{control group}} = \frac{b}{b + d}$$

Risk measurement cannot be done in case-control studies. It is because the incidence data necessary for calculating risks (relative risk, additional risk indicators) cannot be determined. Using the markings of the 2 x 2 contingency table, it is clear that calculating the number of ill people among those exposed (a + b) would be in vain, since the number of people in the control group is arbitrary, and may vary (could be identical with the case group, but may also be several times as many as that).

Due to the above, in case control studies relative risk assessment is done by giving a so-called **odds ratio**. The odds ratio (OR) compares the probability ratios of being exposed and being non-exposed in the case group (a/c) and the control group (b/d). Its mathematical fundamentals were formulated by Cornfield (see reference). Consequently, if the disease is rare (low incidence), the number of cases is low in both the exposed and the non-exposed groups. So, the total number of exposed people (a + b) can be expressed with a good approximation by the number of exposed people in the control group (b), while the total number of the non-exposed people (c + d) is approximately the same as that of the non-exposed people in the control group.

As expressed in a formula:

$$EH = \frac{a/(a + b)}{c/(c + d)} = \frac{a/b}{c/d} = \frac{ad}{bc}$$

Assessment of the results:

OR=1 No relationship

OR>1 Exposure studied is a risk factor

OR<1 Factor studied is a protective factor

As mentioned earlier, additional risk indices cannot be calculated in case control studies. However, by applying the odds ratio an estimate can be given for an **additional risk ratio** here too if the relative risk is replaced by the odds ratio in the formula.

$$ARR = \frac{RR-1}{RR} = \frac{OR-1}{OR} \times 100$$

The main advantages and disadvantages of case control studies can be summarized as follows:

Table 8

Advantages and disadvantages of case control studies

<i>Advantages</i>	<i>Disadvantages</i>
relatively fast and cheap	not suitable for assessing risk factors
excellent for assessing diseases with long latency periods	incidence cannot usually be calculated directly
optimal for studying rare diseases	connection between exposure and disease sometimes difficult to clarify
in connection with one disease several etiological factors can be examined	especially sensitive to distortion (selection and memory)

A good example for a case control study is a Moroccan study carried out involving 800 women in 2008-2010 (400 cases: with breast cancer, 400 control: no breast cancer), in which the effects of the body weight index and the frequency of consuming various foods were investigated in connection with developing breast cancer.

Table 6 Risk factors for breast cancer identified by multivariate analysis		
Characteristics	Odds ratio	95% CI
Body mass index	9.61	6.1-15.15*
Red meat	4.61	2.26-9.44*
Processed meat	9.78	4.73-20.24*
Poultry	0.61	0.46-0.81*
Egg	1.18	0.65-2.19
Fish	0.07	0.02-0.24*
Fruit	0.001	0.00-0.004*
Vegetable	0.82	0.22-3.08*
Cereal	0.83	0.32-2.14
Milk	1.01	0.35-2.97

Odds ratio has been adjusted for age by multivariate logistic regression. Significance threshold $P < 0.05$. *, these results were statistically significant; CI, confidence interval.

Table 9

Factors facilitating the development of breast cancer

Another major initiative is also attributable to results from a case-control study. Discoveries on the causes of the Sudden Infant Death Syndrome (SIDS) were based on a survey conducted in Tasmania, Australia. On the basis of data of 58 case and 120 control infants, it was realised that babies laid on their stomachs had a four times as high risk of SIDS as those in other positions. Moreover, the risk was further increased if infants were laid down to sleep warmly dressed in overheated rooms and/or they had had a form of illness. The results of the study lead to launching campaigns urging parents to lay their babies down to sleep on their backs in order to lower the probability of death by SIDS.

2.6.2.2. Cohort studies

In a cohort study the starting point is also two groups: one exposed and one non-exposed. People in both groups are free of the disease studied and in the investigation it is observed how the illnesses develop in the two groups.

Thus, compared to the case control study the great differences are:

- the individuals in both groups are free of the disease
- the occurrence of the disease is examined, not the risk factors
- the direction of the study is prospective, pointing forward.

The **term cohort** in the classical meaning of the word means a subgroup of the population based on some characteristic remaining unchanged over time. Such a cohort according to an unchanging characteristic can be formed, for example, during examining people born in the same year. In epidemiology, properties characteristic for a cohort are exposure to some risk factor or the lack of the same exposure.

Consequently, the goal of cohort studies is the investigation of the occurrence of a disease in people in the exposed cohort and the non-exposed cohort. In selecting the exposed cohorts the **incubation period** necessary for the development of the disease must be also considered. The incubation period, on the one hand, determines for what period information on the exposure has to be gathered retrospectively. On the other hand, it also affects the length of the **period of following** the groups. It is, obviously, not the same if, for example in the case of lung cancer someone has smoked for half a year or for 15 years.

Prospective	Past (start of the study)	Risk factor present		Risk factor missing	
		Gathering information			
	Present	not ill	ill	not ill	ill

Figure 17
The schematic structure of the cohort study

In many cases it is also reasonable to determine the **degree of exposure**. It may refer to the amount of cigarettes smoked or alcohol consumed as well as the radiation dose suffered. In such cases, subgroups can be created according to the degree of exposure, and the analyses necessary for the assessment can be carried out separately in the subgroups too.

For the selection of the **groups studied**, there two basic methods; Cohort studies based on the **general population** are usually preceded by a cross-sectional study. Thus, the diseased individuals can be separated from those free of the disease and the presence of the risk factors may also be examined. The reliability and preciseness of cohort studies applied on general populations are extremely significant. At the same time, their cost, labour and time requirements are high, which limits the wide use of these studies.

Such a classic applied for a general population was the so-called **Framingham Study**, which regularly examined 5 209 people (both men and women) aged 30-62 of the population of the

town of Framingham (Massachusetts, U.S.A.) in order to clarify the risk factors of coronary disease from 1948. The study was later continued by the investigation of the children and their spouses of the people in the original cohorts (5 124 people) in 1971, and in 2002 they started to follow the third generation, (grandchildren) too. The thorough follow-up over the years lead to the identification of the risk factors. Among other things, it was proved that there was a relationship between high blood pressure, high cholesterol levels, smoking, obesity, diabetes, lack of exercise and CDVs (Cardiovascular Diseases). The initiative has been one of the most significant epidemiological studies so far, and there is no doubt about the importance of the relationships uncovered by it. The risk factors discovered have become organic parts of the effective treatment and prevention strategies in clinical practice.

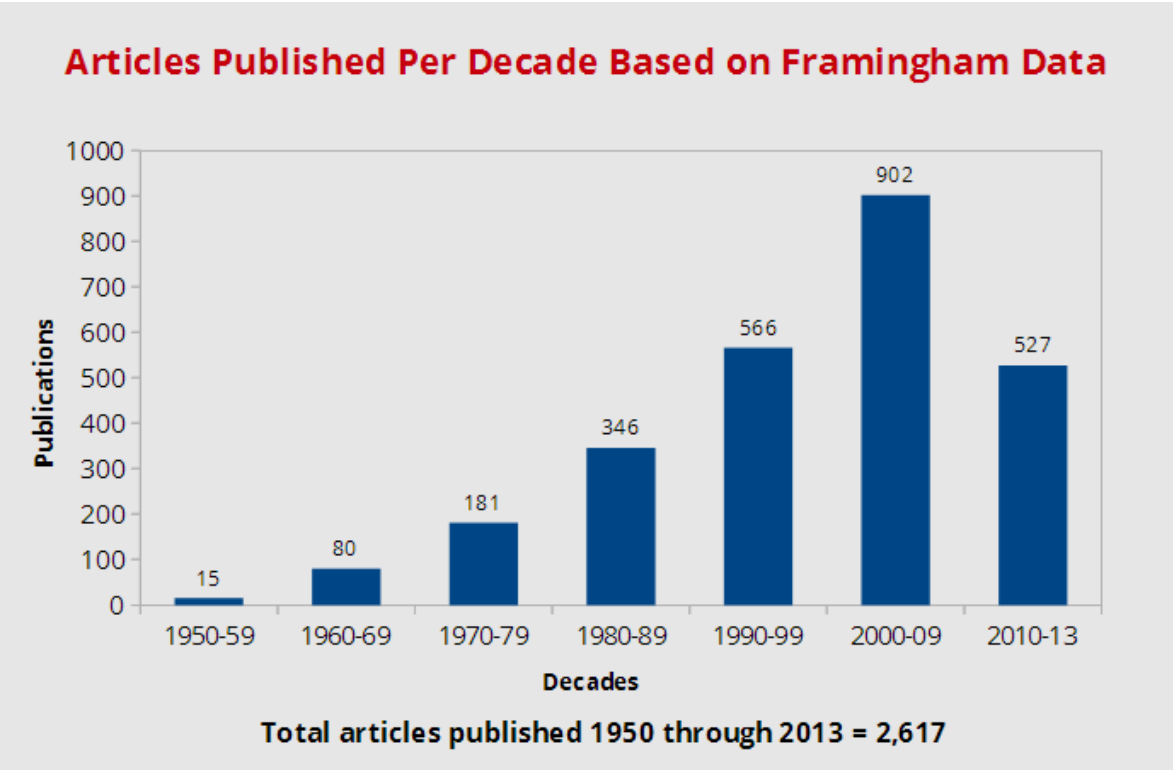


Figure 18

The number of articles published on the basis of the Framingham study (1950-2013)

Another method is the study based on **special exposed cohorts**, by which even those risk factors that are rare in the general population can be analysed. Such special groups are, for example, uranium miners, workers exposed to radioactive radiation or people of other occupational groups.

As a control group, a group which is external from the perspective of the exposure, such as the general population itself or some selected cohort may be used. The great advantage of the general population is that the suitable mortality data are available for comparison. Its application may be limited if the proportion of the special exposed cohort within the population is high. In such cases an external selected cohort serves as the control group. The symbols for *data analysis* are included in the figure presenting the structure of a cohort study. The usual 2 x 2 contingency table is used here too. Some of the individuals healthy at the beginning become cases. Thus, they will be moved to field ‘a’ if they were exposed, or to ‘c’ if they were not exposed.

		CASE		Total:
		Yes	No	
E X P O S E D	Yes	<i>a</i>	<i>b</i>	a + b
	No	<i>c</i>	<i>d</i>	c + d
Total:		a + c	b + d	N = a+b+c+d

Figure 19
The contingency table of cohort studies

In cohort studies the **incidence rate** can be calculated as below:

in the exposed cohort:

$$I_{\text{in exposed cohort}} = \frac{a}{a + b}$$

in the non-exposed cohort:

$$I_{\text{in non-exposed cohort}} = \frac{c}{c + d}$$

Considering that incidence data can be calculated in cohort studies (as opposed to case control studies), **relative risk** (RR) can be calculated with their help.

$$RR = \frac{I_{\text{exposed}}}{I_{\text{non-exposed}}}$$

Assessment of the results:

RR=1 No relationship

RR>1 Exposure studied is a risk factor

RR<1 Factor studied is a protective factor

The **additional risk** (AR) can be calculated as follows:

$$AR = I_{\text{exposed}} - I_{\text{non-exposed}}$$

And the **additional risk ratio** [ARR(%)] like this:

$$ARR = \frac{I_{\text{exposed}} - I_{\text{non-exposed}}}{I_{\text{exposed}}} \times 100 = \frac{AR}{I_{\text{exposed}}} \times 100$$

The main advantages and disadvantages of cohort studies can be summarized as follows:

<i>Advantages</i>	<i>Disadvantages</i>
rare case of exposure can be used	cannot be used in the case of rare disease
can measure several effects of a risk factor	the prospective study is expensive and time-consuming
can also measure transitional relationship between disease and risk factor	if retrospective, it requires suitable data
allows measurement of incidence in exposed and non-exposed cohorts, RR can be calculated based on that	the validity of results is greatly influenced by dropping out (loss)
allows precise exposure measurement	

Table 10

Advantages and disadvantages of cohort studies

One of the most important prospective studies is the so-called British Doctors Study, started by Richard Doll and A. Bradford Hill in 1951. The cohort consisted of 34 439 British doctors, the following period was 50 years (1950-2001). The goal of the study was to compare risks from different smoking habits in men of various ages and to investigate the risk decreasing role of giving up smoking at certain ages. The results of following them for half a century can be seen in the table below, which presents the mortality rates as a result of the smoking habits in 11 main categories according to the causes of death and in total.

Table 1 Cause specific mortality by smoking habit, standardised indirectly for age and study year, for all 34 439 men born in 10th or 20th century (1851-1930) and followed 1951-2001

Cause of death	No of deaths 1951-2001	Age standardised mortality rate per 1000 men/year								Standardised tests for trend (χ^2 on 1 df) ^a	
		Cigarette smokers (vs other smoking habit probably reported)									
		Living non-smokers	Former	Current	Current (cigarettes/day)			Other smokers		Wald	Arnsdorf
Cancer of lung	1062	0.17	0.68	2.40	1.31	2.33	4.17	0.71	1.30	294	452
Cancers of mouth, pharynx, larynx, oesophagus	340	0.00	0.26	0.60	0.36	0.47	1.06	0.30	0.47	68	83
All other neoplasms	3693	3.34	3.73	4.09	4.21	4.87	5.26	3.90	4.22	32	36
Chronic obstructive pulmonary disease	640	0.11	0.64	1.06	1.04	1.41	2.61	0.45	0.64	212	258
Other respiratory disease	1791	1.27	1.70	2.30	1.76	2.85	3.11	1.60	1.67	44	70
Ischaemic heart disease	7628	6.19	7.81	10.81	9.10	10.67	11.11	7.24	7.38	136	133
Cardiovascular disease	2367	2.75	3.18	4.32	3.76	4.30	5.23	3.24	3.28	48	60
Other vascular (including respiratory heart disease)	3052	2.28	2.83	4.15	3.87	4.40	5.30	2.99	3.08	77	94
Other medical conditions	2565	2.26	2.47	3.40	2.94	3.33	4.00	2.49	2.44	34	54
External causes	891	0.71	0.78	1.13	1.08	0.79	1.76	0.89	0.90	17	27
Cause unknown	277	0.17	0.28	0.52	0.38	0.57	0.99	0.29	0.31	16	24
All cause (No of deaths)	30 346 (2917)	19.38 (2054)	24.15 (4688)	35.45 (4688)	29.34 (4688)	34.29 (4725)	40.34 (4725)	23.86 (5713)	25.75 (6882)	689	849

^aValues of χ^2 on one degree of freedom for trend between three or four groups; values >15 correspond to $P < 0.0001$. Wald compares three groups: living non-smokers, former cigarette smokers, and current cigarette smokers. Arnsdorf compares four groups: never smoked regularly, and current cigarette smokers consuming 1-14, 15-24 or ≥ 25 cigarettes/day when last asked.

Figure 20

Disease-specific mortality by smoking habit (Doll et al., BMJ. 2004)

The next table shows the other main direction of the study investigating the effect on mortality of giving up smoking at different ages compared to the mortality data of doctors who have never smoked and those who smoked regularly. According to their results quitting smoking at 60, 50, 40 or 30 years of age increases life expectancy by approximately 3, 6, 9 or 10 years, respectively.

Table 5 Overall mortality among never smokers, ex-smokers, and continuing cigarette smokers in relation to stopping smoking at ages 35-64 (men born 1900-1930 and observed during 1951-2001)

Age range (years)	Lifelong non-smokers	Ex-cigarette smokers, by age stopped			Continuing cigarette smokers	Mortality ratio (cigarette smoker v non-smoker)
		35-44	45-54	55-64		
35-44	1.6† (155)	—	—	—	2.7 (150)	1.6†
45-54	3.8 (145)	3.4† (95)	—	—	8.5 (487)	2.3
55-64	8.4 (290)	9.0 (132)	16.4† (239)	—	21.4 (703)	2.5
65-74	18.6 (528)	22.7 (262)	31.7 (331)	36.4 (250)	50.7 (722)	2.7
75-84	51.7 (665)	53.1 (316)	69.1 (370)	78.9 (298)	112.2 (453)	2.2

Division of the rate by the square root of the number of deaths indicates its standard error.
 †Mean of two five yearly age specific rates.
 ‡Marked rates are P<0.001, significantly lower than in continuing cigarette smokers (P<0.00001 for all unmarked non-smokers and ex-smoker rates).

Figure 21

Overall mortality among non smokers, ex-smokers and continuing cigarette smokers (Doll et al., BMJ. 2004)

2.6.3. Intervention studies

In intervention (experimental) epidemiological studies experimental methods are applied to confirm the results of analytical epidemiology. Those interventions are carried out in human populations under close ethical control. Intervention studies strive to verify causal relationships between assumed aetiological factors and the occurrence of diseases. Such an intervention at population level is the addition of iodine to common salt in order to prevent goitre.

2.6.3.1. Randomized controlled trials

In randomized controlled studies procedures to be used later on particular, so-called reference populations, are examined. Such a reference population may be, for example, women past the child bearing age, and the subject of the study could be a medicine developed for that target population.

During the randomized study the above-mentioned reference population has to be defined precisely first, then from that population a volunteer sample in which the investigation is carried out is selected. At this point it is important to note that the participants of the trial have

to be informed very thoroughly and professionally about every detail of the study. After that, of course, some of those in the sample do not agree to take part in the trial, they drop out.

The treatment group and the control group have to be selected randomly from those agreeing to participate. That means that both groups contain patients chosen from the same sample, put into which group is only determined by chance.

Next, the intervention, which may be either preventive or therapeutic by nature (operation, medication, diagnostic method, etc.) is carried out in the treatment group. In the case of the control group there are several options: either nothing is done, a placebo is given or an intervention of another kind is administered. It must be stressed again that the two groups (experimental and control group) may only differ at that point, regarding the intervention factor examined. The principle of double-blind trials means that neither the patients nor the people conducting the study know who is in the experimental group or the control group. Nevertheless, it is in the patients' interest that their treating physicians (who are not involved in the study) should know what treatment their patients are receiving.

The dropping out of patients during the trial may, however, happen not only in the first stage but in any phase. That is why it is essential to examine the circle of patients dropping out to see if the equal proportions between the experimental and the control groups created at the beginning remain till the end of the trial.

Participants (inclusion and exclusion criteria)	Randomization Blinding	INTERVENTION	Expected result
			Not expected result
		CONTROL (placebo)	Expected result
			Not expected result
Past (start of study)			Present (end of study)

Figure 22

The flowchart of randomized controlled trials

The Hungarian-born László Tabár and his colleagues studied the effect of screening by mammography on breast cancer mortality in a randomized controlled clinical trial at population level in two counties in Sweden (Östergötland, Kopparberg). By following the population for 7 years they found that the ratio of stage II or higher-stage advanced breast cancer cases had decreases by 25 %, and mortality from breast cancer had decreases by 31 %.

TABLE I—NUMBER OF WOMEN INCLUDED IN THE STUDY IN THE 2
COUNTIES BY AGE AT ENTRY

Age- group	Study group			Control group		
	Öster- götland	Koppar- berg	Total	Öster- götland	Koppar- berg	Total
40–49	10 312	9625	19 937	10 625	5053	15 678
50–59	11 918	11 863	23 781	11 416	5632	17 048
60–69	11 646	12 153	23 799	10 920	5674	16 594
70–74	5158	5410	10 568	4975	2487	7462
(≥75	7967	8338	16 305	7997	3812	11 809)*
Total 40–74	39 034	39 051	78 085	37 936	18 846	56 782

*Not included in the present analysis because compliance was poor.

Figure 23

The initial patient population of the 'Tabár' randomized controlled study of two Swedish counties (Tabár, 1985)

TABLE VI—DEATHS FROM BREAST CANCER IN STUDY AND CONTROL POPULATIONS*

—	Kopparberg county			Östergötland county		
	Deaths	Popula- tion	Relative risk	Deaths	Popula- tion	Relative risk
Study group	51	39 051	0.63	36	39 034	0.74
Control group	39	18 846		47	37 936	

Combined χ^2 on 1 d f = 6.17, p = 0.013 (2-sided).

Combined estimate of relative risk = 0.69, 95% confidence interval (0.51, 0.92).

*Women aged 40–74 at entry.

Figure 24

The effect of screening by mammography on deaths from breast cancer in the 'Tabár' randomized controlled study of two Swedish counties with a 7-year period of following (Tabár, 1985)

20 years of following period in the study in the two Swedish counties confirmed the previous favourable experiences concerning the decrease of deaths from breast cancer.

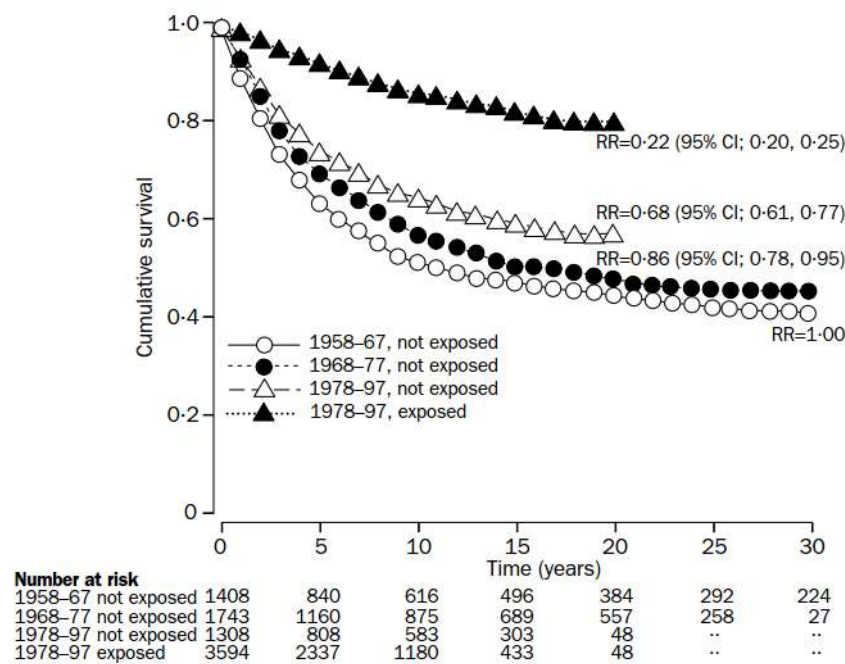


Figure 2: Cumulative survival of breast cancer patients aged 40–69 years at diagnosis

Figure 25

The effect of screening by mammography on deaths from breast cancer in the 'Tabár' randomized controlled study of two Swedish counties with a 20-year period of following (Tabár, 2003)

2.6.3.2. Population intervention studies

The North Karelia Project was launched in the eastern province of Finland in 1972 to lower the frequency of mortality from circulatory diseases, which was exceptionally high even compared with the national average. The programme was organized and carried out at a communal level. Consequently, the representatives of the inhabitants of the province had a significant role in planning and implementing changes. Most of the practical work was done by the citizens of the province (Medical Officers for Health, general practitioners, nurses, district nurses, NGOs).

As a result of the programme, smoking decreased considerably among men. In 1972 the percentage of middle-aged smokers was 52%; by 1997 it fell to 31 %. The number of deaths from coronary heart disease decreased by 73 % among the middle-aged male population in the province. The remarkable changes taking place as a result of the programme can be seen in the table below.

TABLE 1 Mortality changes in North Karelia in 1970-1995 (per 100 000, 35-64 years, men, age adjusted).

	Rate in 1970	Change in 1970-1995
All Causes	1509	-49%
All cardiovascular	855	-68%
Coronary heart disease	672	-73%
All cancers	271	-44%
Lung cancer	147	-71%

Table 11

Mortality changes in North Karelia (1970-1995)

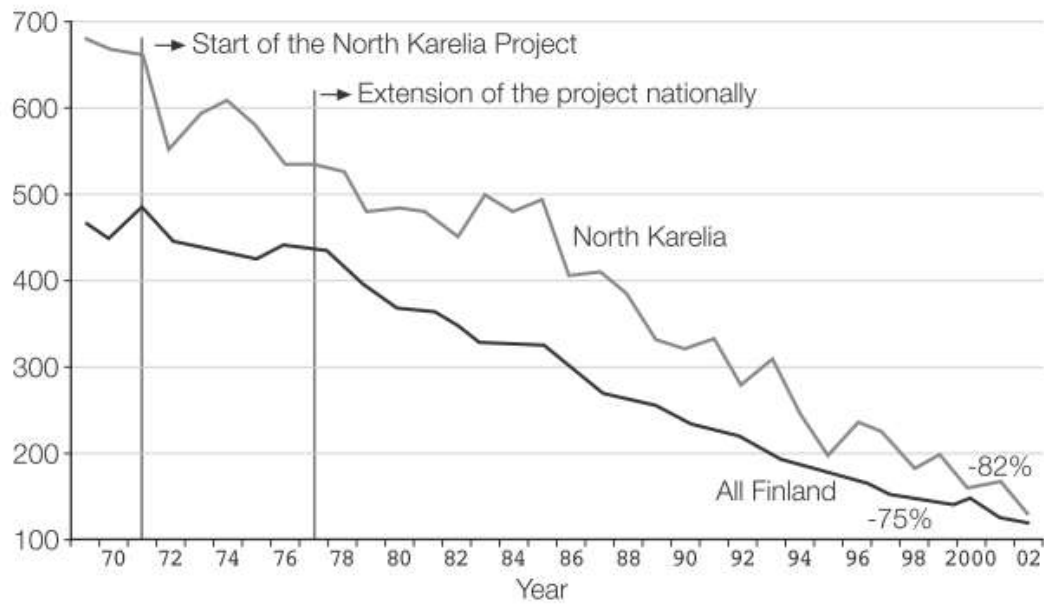


Figure 3.4 Coronary heart disease mortality changes in the North Karelia province and the whole of Finland from 1970 to 2002 in men aged 35–64 years²²

Table 12

Mortality changes in North Karelia and Finland (1970-2002)

As you could see above, in the international practice there are numerous examples of public health interventions by which great improvements had been reached concerning the indicators of population health status. They could also serve as example Hungarians for Hungary.

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3. TYPES AND METHODS OF HEALTH ECONOMICS RESEARCHES (I. BONCZ, CSÁKVÁRI T, ENDREI D)

In the healthcare system it is often difficult to measure costs and benefits obtained for them. Although, in complex systems like the healthcare system the definition and separation of the costs is not an easy task, the real problem is the quantification of the benefits (profit) side. The most important problem is the measurement of the output of healthcare treatments and interventions. In the book the methodological questions of costs calculation (see László Gulácsi) and those of measuring quality of life (Márta Péntek) are introduced in separate chapters. Further publications discuss the issues of the field of health economics in more detail.

In this chapter you will find an overview of health economic analyses, where - as a main rule - the costs and the benefits (health benefit) are assessed together.

3.1. THE ROLE AND SIGNIFICANCE OF HEALTH ECONOMIC ANALYSES

In the course of centuries of development in medicine one of the great challenges has been finding effective cures. As a result of the technological development and social transformation in the 20th century more and more effective but, at the same time, more and more expensive medical procedures (diagnostic and therapeutic interventions, medicines, medical accessories etc.) have appeared and have become available to wider and wider layers of society. As a result of the new technologies, population ageing and increasing demands on the part of the citizens, the health costs of certain countries have increased remarkably and an ever increasing part of communal funds is spent on financing healthcare expenditure.

Simultaneously with the growing expenses, there has also been an increasing demand or pressure to distribute the available resources not only according to the occurring medical-professional demand but also in consideration of the aspects of the economy. The classical set of conditions included three main criteria ('obstacles') in healthcare technologies (e.g. medicines): quality ('first obstacle'), safety ('second obstacle') and efficacy ('third obstacle'). In order to overcome these three obstacles there is a well-designed set of criteria operating in the developed countries. However, in financial decision-making, when available and usually

scarce funds have to be decided on, a fourth criterion, 'obstacle' has also developed: effectiveness and cost-effectiveness.

During the investigation of the fourth 'obstacle', i.e. effectiveness and cost-effectiveness, the financing organisations are not only interested in efficacy information from the usual clinical trials (normally randomized controlled trials) but also in the effectiveness the given technology shows effective routine clinical practice and at what costs it can achieve that. Thus, the primary purpose of this fourth 'obstacle' is the scientific support of decision-making about the allocation of resources, and its tools are the introduction of health economic analyses.

In several European Union member countries (e.g. the UK, Holland, Sweden, France, etc.) health economic and healthcare technological analyses get a greater and greater role. One of the influential European institutions in the field is the NICE (National Institute for Clinical Excellence), found in the United Kingdom.

In Hungary the guideline of the Ministry of Health for preparing health economic analyses was published in 2002. This guideline determines the methodological questions of health economic analyses, thus ensuring professional standards for various analyses. The organisational background of health economic and healthcare technological analyses was provided by the Healthcare Strategical Research Institute (ESKI, earlier Medinfo) from 2004. Nowadays, following repeated changes, the Technology Assessment Department of the National Institute of Pharmacy and Nutrition (OGYÉI) is responsible for the healthcare technological assessment of requests for social security subsidised prices. Health economic analyses were introduced into administrative decision-making together with Hungary's accession to the European Union, by evaluating requests for social-security subsidised prices for medicines in the first phase, by adopting the so-called transparency directive of the European Union (Directive 89/105/EEC of the Council of the European Communities on Transparency) in Hungary. The first Hungarian books on health economics were also published at that time.

It must be stressed that health economic analyses do not constitute a practical tool for decreasing healthcare expenditure; their role is rather to allow the comparison of the various options during reaching decisions on adopting medicines by the social security.

The figure below illustrates where the preparation / implementation of health economic analyses stands the life cycle of medicines. As you can see, the approximately 10-year period of developing a medicine is followed by registration, pricing and obtaining price support by

the social security. In that phase the period between registration/pricing and obtaining social security subsidising for the price is of great significance. It is because the manufacturer and the marketing authorization holder are interested in the same, i.e. that the period between registration and obtaining social security subsidising should be as short as possible. If it takes too long (years), the period of patent protection becomes considerably shorter and the generic competitors appear too soon.

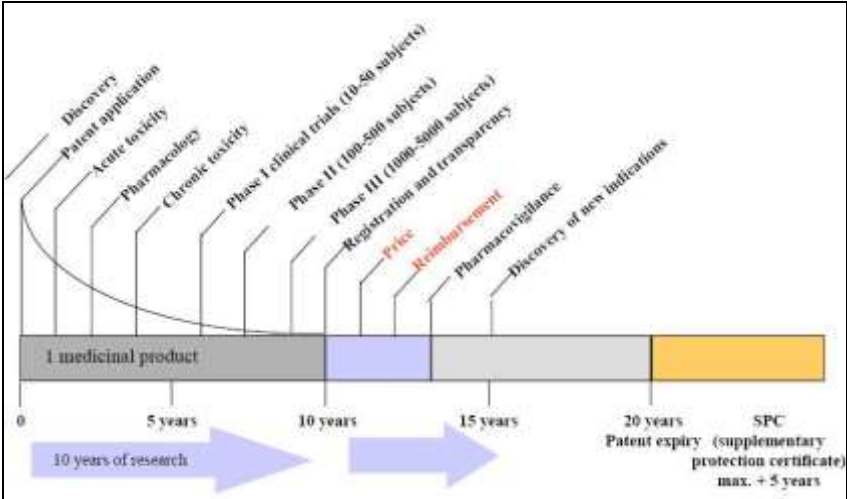


Figure 1

The life cycle of medicines from discovery (Source: Recherche & Vie, LIM, AGIM)

The following figure illustrates the average time passed between the publication of the clinical results and that of the health economic results of various trials (n=41). This delay is mostly between 13 and 24 months in the cases examined. That means that the publication of the clinical trial results is followed by the publication of the health economic results 13-24 months later.

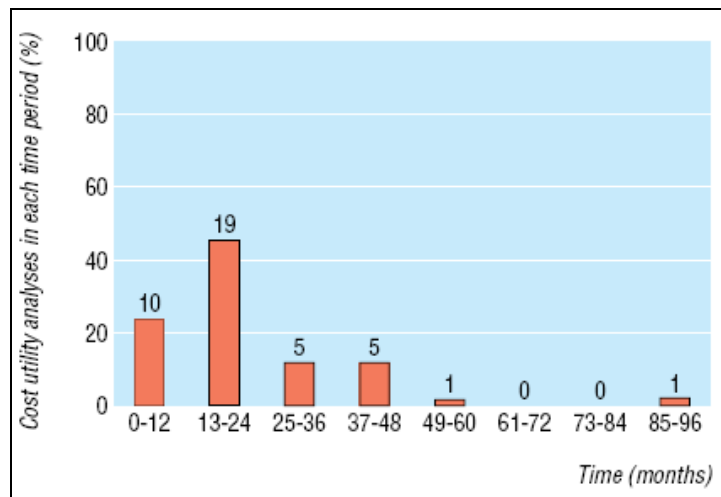


Figure 2

The average time between the publication of the clinical results and that of the health economic results of various trials (n=41) (months).

(Source: Greenberg D et al. BMJ 2004;328:1536–7.)

3.2. THE MAIN TYPES OF HEALTH ECONOMIC ANALYSES

In health economic analyses two main questions need to be clarified according to the interpretation of Drummond et al.:

- are both the costs and effectiveness of healthcare technologies examined?
- are two or more alternatives compared?

Unless at least two health technologies are compared, one has to talk about a partial analysis only. If at least two health technologies are compared but only either the expenses or the effectiveness is investigated, it is also considered to be a partial health economic analysis.

One can talk about a complete health economics analysis if:

- at least two alternatives are compared
- both the costs and the results are examined.

Table 1

Categories of health economic analyses (Drummond et al., 1997)

		ARE BOTH THE COSTS AND THE FINAL RESULTS EXAMINED?		
		NO		YES
ARE TWO OR MORE ALTERNATIVES COMPARED?	NO	<i>PARTIAL ANALYSIS</i>		<i>PARTIAL ANALYSIS</i>
		It only examines final results	It only examines costs	Cost-result analysis
	Description of results	Description of costs		
	YES	<i>PARTIAL ANALYSIS</i>		<i>COMPLETE ANALYSIS</i>
Assessment of efficacy or effectiveness		Cost analysis	Cost-minimization analysis Cost-effectiveness analysis Cost-utility analysis Cost-benefit analysis	

According to the above 4 main types of health economic analyses can be distinguished:

- Cost-minimization analysis
- Cost-effectiveness analysis
- Cost-utility analysis
- Cost-benefit analysis

Table 2

The main types of complete health economic analyses

ENGLISH TERM	HUNGARIAN TERM	OUTCOME	COSTS
Cost-minimization analysis (CMA)	költség-minimalizációs eljárás	There is no difference in the outcome of the procedures examined.	Only procedure prices need to be compared. The procedure with the lowest price is to be selected.
Cost-effectiveness analysis (CEA)	költség-hatékonysági elemzés	Identical outcome indicator concerning different procedures examined (e.g. life years gained)	Costs/life years gained
Cost-utility analysis (CUA)	költség-hasznosság elemzés	Both the quantity and the quality of the outcome are interesting (e.g. Quality adjusted life years, QALY; Disability adjusted life years, DALY)	costs/QALY or costs/DALY
Cost-benefit analysis (CBA)	költség-haszon elemzés	The results in kind are expressed in money in a unified manner.	costs/costs

3.2.1. Cost-minimization analysis

The basic criterion for using cost-minimization analyses is that there must not be any difference between the outcomes of the health technologies studied. Its typical field of application is making decisions on subsidizing medicine prices, when besides the original (developed by innovative research) pharmaceutical products, generic products also appear after the termination of the patent protection period. Considering that in both the original and generic medicines the same active substance molecule can be found, in most cases there is no difference in the outcome due to bioequivalence.

As a consequence, here the funding organizations (e.g. health insurance funds, state healthcare services or private health insurances) only consider the price when making a decision on subsidization. In active substance-based reference pricing groups of products with the same active substance are formed, then the product with the cheapest price is given a fixed amount of subsidy.

Merész et al. have carried out the cost-minimization analysis of analogue basal insulins, comparing the insulin glargines and detemirs available in Hungary. According to meta-analysis and meta-regression results the annual cost of a type-2 diabetes patient with an average weight (90 kg) using insulin glargine is HUF 993 452 less, calculated with a gross purchase price, for the funding organization than when using insulin detemir.

Parameter	Data	Explanation
Difference in daily dose per bmkg	0.26 NE	Cochrane analysis
Weight of average Hungarian diabetes patient	90 kg	expert estimate
Insulin saved per one average Hungarian diabetes patient	23.4 NE	$0.26 \times 90 \text{ kg}$
Cost of one NE detemir based on gross selling price	HUF 10.84	
Daily therapeutic cost difference in favour of glargin	HUF 253.63	$23.4 \text{ NE} \times 10.84 \text{ HUF}$
Annual saving per patient with 100% OEP support	HUF 92 639	$365.25 \times \text{HUF } 253.63$

Figure 3 Differences in medication costs

Table 3

Cost-minimization analysis results (Merész et al., 2012)

6. táblázat. A gyógyszerköltések különbségének bemutatása

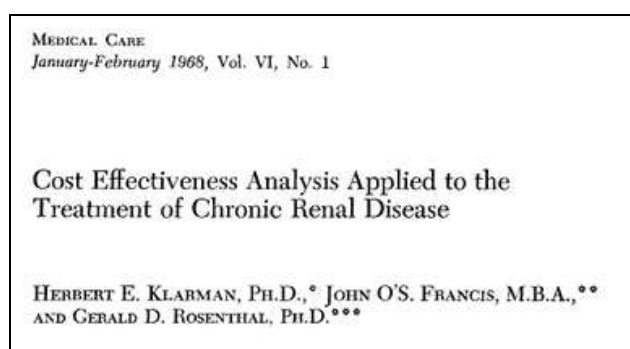
Paraméter	Adat	Magyarázat
Egy ttkg-ra jutó napi dóziskülönbség	0,26 NE	Cochrane-elemzés
Átlagos magyar cukorbeteg tömege	90 kg	szakértői becslés
Egy átlagos magyar cukorbetegnél napi inzulinmegtakarítás	23,4 NE	0,26 NE × 90 kg
Egy NE detemir költsége bruttó fogyasztói ár alapján	10,84 Ft	
Napi terápiás költségkülönbség glargin javára	253,63 Ft	23,4 NE × 10,84 Ft
Egy betegre jutó éves megtakarítás 100%-os OEP-támogatás mellett	92 639 Ft	365,25 × 253,63 Ft

3.2.2. Cost-effectiveness analysis

It is the comparative assessment of two or more alternative procedures designed to reach the same change in health status, where the costs of the procedure expressed in money are compared to requirements expressed in other measurable forms than money (e.g. life years gained, number of deaths prevented, days without patients, additional years of lengthened life, cases screened, etc.). In this analysis two interventions with identical outcomes and known costs are compared.

In other words, the cost necessary for reaching a unit of result is determined (e.g. cost/life years gained). It can also be interpreted inversely (life years gained/cost), which is of significance in the case of a fixed budget.

One of the first health cost-effectiveness analyses was published by Klarman et al. in 1968-ban, and it is regarded as one of the prototypes of health economic analyses. In Hungary the first cost-effectiveness analyses from the perspective of the funder was published by Boncz et al. for the National Health Insurance Fund of Hungary (OEP) on screening by mammography and cervical cancer screening.

**Figure 4**

One of the first health cost-effectiveness analyses (Klarman et al. 1968)

3.2.3. Cost-utility analysis

The value of applying a technology expressed in costs is compared to the results obtainable, by comparing the results to the number of Quality Adjusted Life Years (QALY) lived after the application of the technology.

That means that two alternative health technologies are examined here too, but it is not only the change in life years that is measured, like in the case of a cost-effectiveness analysis, but also the change in the quality of life.

Here QALY (Quality Adjusted Life Years) or similar DALY (Disability Adjusted Life Years) can be used as indices.

McQueen et al have carried out the cost-effectiveness analysis of the continuous glucose monitor (CGM) on adults suffering from type 1 diabetes in the United States. As a comparator they used fingertip blood glucose monitoring (SMBG).

In their analysis they used the Markov cohort model, in which 12 different diabetes disease statuses are used, with 1-year cycles, over a 33-year period. In the analysis of a social aspect the average age of the population was 40, with an average of 20 years of diabetes history. The costs were measured in US dollars (2007), while effectiveness in Quality Adjusted Life Years (QALY). The input parameters used in the model were taken from the literature, while the utility values from the EQ-5D catalogue. The probability values came from the Diabetes Control and Complications Trial (DCCT), the United Kingdom Prospective Diabetes Study (UKPDS) and the Wisconsin Epidemiologic Study of Diabetic Retinopathy. Both for the costs and the QALY values a 3 % discount rate was applied. Probabilistic sensitivity analyses with one and several variables were carried out by running 10 000 Monte Carlo simulations.

The continuous glucose monitor (CGM) compared to fingertip blood glucose monitoring (SMBG) showed a gain of 0.52 QALY and USD 23 552 additional costs, which altogether resulted in a cost-effectiveness (ICER) value of 45 033 USD/QALY. Assuming a 100 000-USD willingness to pay threshold, CGM used with an intensive insulin therapy was cost-effective in 70 % of the Monte Carlo simulations.

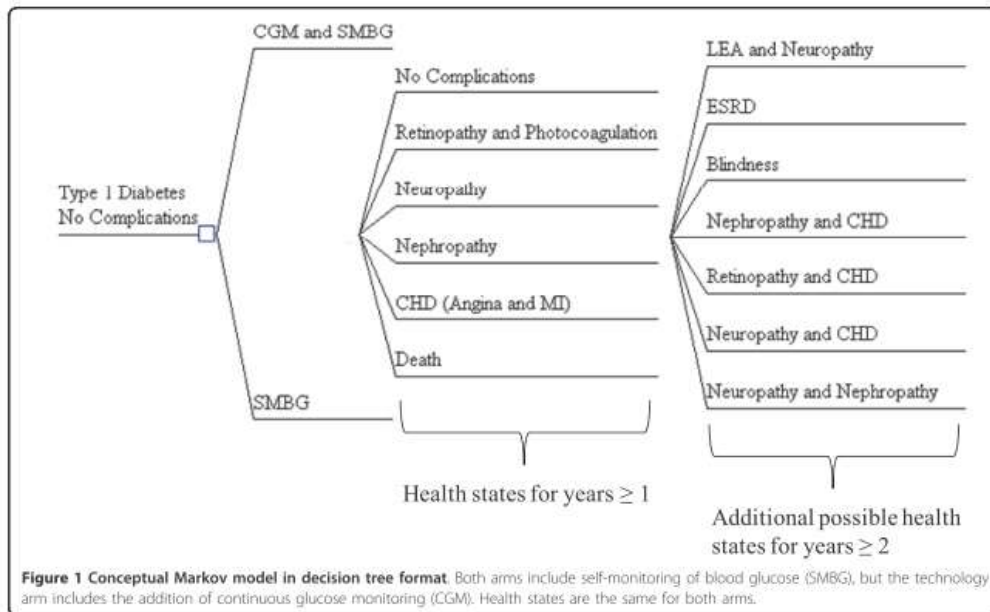


Figure 5

The structure of the Markov model in McQueen’s analysis (McQueen et al., 2011)

Table 4

The base case result of the Markov model in McQueen’s analysis (McQueen et al., 2011)

Table 2 Expected Cost and Effectiveness of Continuous Glucose Monitoring (CGM) and Self-Monitoring of Blood Glucose (SMBG)

Strategy	Expected Cost in 2007 \$US (range)*	Expected Effectiveness QALYs (range)*	Incremental cost-effectiveness ratio (ICER)
SMBG	470,583 (397,782 - 550,598)	10.289 (9.615 - 10.957)	
CGM and SMBG	494,135 (420,381 - 571,631)	10.812 (9.894 - 11.887)	US \$45,033/QALY

*95% credible ranges based on the results from the 10,000 Monte Carlo simulations

3.2.4. Cost-benefit analysis

It is the comparison of the costs of a health programme or medical technology examined expressed in terms of money to the savings that can be achieved by it expressed in money, i.e. the consequences of not doing the programme expressed in money. It causes serious difficulty that the method measures both the input and the output sides in terms of money.

Deng et al. have carried out the cost-benefit analysis of Internet Blood Glucose Monitoring (Internet Blood Glucose Monitoring Service, IBGMS) compared to standard diabetes care. According to their hypothesis the development of the Internet Blood Glucose Monitoring Service was significant, and its effects could also be felt in clinical practice, e.g. by the reduced number of doctor-patient encounters. In their analysis they investigated the costs associated with doctor-patient encounters: travel expenses and the cost of missed work.

The intervention group using Internet facilities (IBGMS) showed considerably lower expenses than the group receiving standard care (131.26 USD versus 210.89 USD), although the difference was not significant ($P = 0.128$). In the intervention group both the costs of transportation and the costs caused by missed work were lower compared to the standard therapy group.

Table 5

The result of the cost-benefit analysis (Deng et al., 2015)

	Cost/Person		
	Control	Intervention	P Value
Total Cost	210.89 ^a	131.26	0.128
Cost of Transportation	31.70	24.78	0.289
Cost of Missed Work	179.19	106.48	0.294

^a US Dollar.

A special area of cost-benefit analyses is the analysis of health investments realized from European Union support. The National Development Agency published a separate methodological guide for the cost-benefit analysis of health investments funded by EU sources (General methodological guide for cost-benefit analyses). This methodological guide was a Hungarian version of a similar guide of the European Union.

According to the interpretation of the guide: “The goal of an economic cost-benefit analysis is the examination of the social utility and the costs of a selected technical solution. Considering that in this analysis financial benefits and costs have to be complemented or replaced by social costs and benefits, it can also be regarded as a social-economic analysis.”

In the case of European Union development projects the relationships of the individual elements of a cost-benefit analysis and the purposes, places, outputs and results of the elements are illustrated by the figure below.

		Objective	Location	Output	Conclusion
Options analysis	Cost-effectiveness analysis	Selection of technically feasible and legally appropriate project options	On the basis of the study phase and the technical cost estimates and before the detailed technical planning and authorizations	In case of cost-effectiveness analysis: option with least cost	The selection of the most appropriate, effective technical solution, which is the basis of further elaboration
	Multi-criteria assessment			In case of multi-criteria assessment: a weighed score	
	Simplified economic cost-benefit analysis			In case of simplified economic cost-benefit analysis: present value of net benefits	
Financial analysis		Study of financial return	In detail for the selected option, based on the technical cost estimates and market analyses, according to legal and contractual regulation	Financial performance indicators NPV, FRR, BCR	<ul style="list-style-type: none"> • Determination of investment costs • Determination of the amount of EU grant, own resource need and other grants/supports
		Study of financing, sustainability		Cash flow	
		EU grant calculation			
Analysis of social costs and benefits	Economic cost-benefit analysis	Study of eligibility	In detail for the selected option, based on the detailed plans, studies, technical cost estimates, environmental impact and demand analyses	Economic performance indicators NPV, ERR, BCR	<ul style="list-style-type: none"> • Justification of project grant • Comparability with other projects based on indicators calculated
	Multi-criteria assessment	Study of social utility of selected option		Weighed score based on the criteria of multi-criteria assessment	
Sensitivity, scenario and risk analysis		Study of reliability of cost-benefit analysis	As part of all three analyses	<ul style="list-style-type: none"> • Critical variables • Determining threshold values • Quantified risks 	<ul style="list-style-type: none"> • Determining critical points of prognoses • Risk assessment • Justification of technical supplies • Justification of choice of option

Figure 6

The elements of the cost-benefit analyses of European Union investment projects (NFÜ, 2008)

3.3. FINANCING THRESHOLD VALUE

By comparing the results of health economic analyses information is obtained in connection with decision-making.

The results of primary health economic analyses are usually displayed in so-called league tables. George et al. studied the decisions of the Australian Pharmaceutical Benefits Advisory Committee (PBAC). They summarized the results of the cost-effectiveness analyses of 22 medicines, and the unit of measure used was the cost of one life saved expressed in Australian dollars. The table below illustrates the decision of the Committee. It can be seen that the first 11 medicines with the most favourable cost-effectiveness indicators received the support of the social security. That means that drawing an imaginary line, the products with favourable cost-effectiveness ‘above the line’ got social security support. Below the line, however, the situation is not that obvious: there are rejected products with more favourable cost-effectiveness indicators and there are also ones with very unfavourable (very high) cost-effectiveness indicators that were granted social security support.

The reason for that is that besides cost-effectiveness numerous other aspects need also to be considered during decision-making about funding-subsidizing. It very often happens that there are not enough funds even for a medicine with more favourable cost-effectiveness in a ‘poorer’ country at a lower level of development, since there are no available budgetary funds available. On the other hand, a medicine with unfavourable cost-effectiveness may also receive social security support if, e.g. there is no other medicine for that particular disease and it is the patients’ only chance. Typically such medicines are the ones used for the treatment of rare congenital enzyme diseases.

Table 6

League table containing the results of the cost-effectiveness analyses of various medicines
(George et al., 2001)

Number	Incremental cost per additional life-year gained at 1998/1999 prices (\$AU)	PBAC decision
1	5517	Recommend at price
2	8374	Recommend at price
3	8740	Recommend at price
4	17387	Recommend at price
5	18762	Recommend at price
6	18983	Recommend at price
7	19807	Recommend at lower price
8	22255	Recommend at price
9	26800	Recommend at price
10	38237	Recommend at price
11	39821	Recommend at price

12	42697	Reject
13	43550	Reject
14	43550	Defer
15	43550	Recommend at price
16	56175	Reject
17	57901	Recommend at price
18	63703	Reject
19	71582	Recommend at price
20	75286	Recommend at price
21	85385	Recommend at lower price
22	88865	Reject
23	98323	Reject
24	229064	Recommend at lower price
25	231650	Reject
26	256950	Reject
<p>\$AU = Australian dollars. The average interbank exchange rate to US dollars for 1998/1999 was 0.63772 (range 0.68760 to 0.54850). PBAC = Pharmaceutical Benefits Advisory Committee.</p>		

3.4. THE ROLE OF HEALTH ECONOMIC ANALYSES IN DECISION-MAKING

As seen above, health economic analyses make the costs of the application of various health technologies (medicines, instruments, diagnostic and therapeutic procedures, etc.) comparable with the health benefits achievable by them. These analyses show decision-makers what costs and advantages supporting a given health technology by social security, i.e. funding it from public sources, would involve within a given period.

In Hungary health economic analyses are carried out according to the guidelines of the Ministry published on the basis of the recommendations of the Hungarian Health Economic Society (META).

Apart from cost-effectiveness, however, other aspects need to be examined during decision-making too, and the complex assessment of those may lead to decisions on price subsidies also acceptable to the society. Thus, the key issue here is not the mere cost-effectiveness but the transparency of decision-making and the transparent presentation of the aspects considered and assessed in reaching the decision.

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4. METHODOLOGICAL QUESTIONS OF COSTS CALCULATION (L. GULÁCSI)

4.1. 1. THE GOAL AND PROCESS OF COSTS CALCULATION

The purpose of costs calculation is the assessment of expenses related to healthcare, in which both the direct and the indirect costs have to be taken into account. (Gulácsi et al., 2006; Gulácsi et al., 2012)

The process of costs calculation consists of three well-identifiable phases, which are the following:

- identification of the relevant resource (cost) elements,
- measuring the utilization of the identified resources,
- determining the value of the resources (expressing them in money).

It is advisable to do these three phases of costs calculation in separate, successive steps. However, already in the phase of identifying the resources, one must remember that only cost elements whose utilization can be measured in any way or that have a unit cost or are at least calculable somehow have to be identified. It is also sensible to publish the result of the costs calculation in that form. (Tables 7 and 8) Scientific literature of good quality also publishes the results of costs calculations in this structure. This should be paid attention to while choosing literature, and publications which do not present the results of costs calculations in this way should be avoided.

4.1.1. Identification of the relevant resource (cost) elements

In the analysis of the costs of therapies and interventions, all costs have to be taken into account regardless of who actually incurs them and where in the society (in which sector) they occur. To this end, one must know the health technological elements necessary for performing the intervention (staff, instruments, equipment, medication), the epidemiological data (the process of the disease before/during/after treatment and the need for resources in these periods) and the length of the process (treating the patient, monitoring). Also, the

changes in the patients' capacity (short- and long-term) and whether the given treatment requires further interventions, which results in further additional costs (also to be assessed), need to be considered. As a first step of the health economic analysis it is advisable to make a draft of all the possible statuses of the disease as well as all the likely therapeutic measures.

Two examples demonstrate the above well. One of them present the costs results of the research that was done on the basis of the cross-sectional study of 100 outpatients with diagnosed epilepsy treated in a Budapest epilepsy centre. (Table 7) The purpose of the research was to study the individual and social costs related to epilepsy disease (Péntek et al., 2013) The other (Table 8) shows the result of the research, whose goal was the analysis of the disease costs of patients with serious psoriasis coupled with moderate arthritis psoriatica involving 57 patients of two university dermatological clinics. (Gulácsi et al., 2014)

When all the resources connected to a disease or necessary for carrying out a given intervention are known, one can decide whether all elements need to be taken into account in the economic analysis or some of them should be left out due to their lack of importance. Nevertheless, at the stage of identifying the resources it is advisable to list and document them too.

Table 7 The utilization of care services related to epilepsy disease and their annual average costs per patient (HUF, 2012)

Breakdown of costs		Cost elements	Annual average cost per one epilepsy patient		Patients receiving the given service	
			HUF/patient	Breakdown %	number of patients	total occasions/year
Direct healthcare costs 226 920 HUF/patient/year (33%)	Medical care	Visit by GP	3 970	0.58	47	258
		Visit by specialist	6 666	0.98	100	352
		Hospital care	29 668	4.37	18	33
	Medicines	Various medicines	172 272	25.36	97	NA
	Diagnostic costs	X-ray, CT, MR, carotis UH, SPECT, EEG, laboratory	11 284	1.66	76	327
Services not supported by social security	Private doctor, naturopath, other	3 060	0.45	5	21	
Direct non-healthcare costs, 119 226 HUF/patient/year (18%)	Transportation costs	Car, public transport, ambulance	17 978	2.65	100	NA
	Help by other person	Informal care for self-sufficiency	101 248	14.90	17	27 612* (hour)
Indirect costs 333 251 HUF/patient/year (49%)	Costs from missed work	Income foregone due to disability retirement	327 666	48.23	22	NA
		Income foregone due to sick leave	5 585	0.82	7	720 (hours)
		Total	679 397	100.00	NA	NA

*The total number of hours of informal care received by the 17 patients, projected for one year.

NA=not applicable

Source: Péntek et al., 2013

Table 8 Annual average costs of a patient with serious psoriasis coupled with moderate arthritis psoriatica (HUF, 2012)

Breakdown of costs		Cost elements	Average cost per one patient	
			HUF/patient/year	Breakdown %
Direct healthcare costs 1 929 735 HUF/patient/year (75%)	Medical care	Visit by GP	10 260	0.4%
		Visit by specialist	13 395	0.5%
		Hospital care	39 330	1.5%
	Medicines	Biological	1 814 310	70.9%
		Methotrexate	8 265	0.3%
		Other systemic	17 100	0.7%
	Services not supported by social security	Non-prescription products	7 410	0.3%
Other services not supported by social security, e.g. private doctor		19 665	0.8%	
Direct non-healthcare costs, 102 315 HUF/patient/year (4%)	Transportation costs	Transportation by ambulance	9 120	0.4%
		Car, public transport	2 565	0.1%
		Transportation voucher	1 140	0.0%
	Help by other person	Informal care for self-sufficiency	89 490	3.5%
Indirect costs 526 965 HUF/patient/year (21%)	Costs from missed work	Income foregone due to sick leave	21 090	0.8%
		Income foregone due to disability retirement*	505 875	19.8%
Total costs			2 559 015	100%

*due to psoriasis

Source: Gulácsi et al., 2014

4.1.2. Measuring the use of resources

In the measurement of the use of resources the utilisation of the individual resource elements have to be analysed.

If the measurement is done from the point of view of the society, it must be ensured during data collection that data routinely available include all the relevant resource elements regardless of at what level and in what “treasury” of healthcare (OEP) or whether outside the healthcare system they occur. In addition, it may be necessary to take, for example, travelling costs, the costs of medicines paid by patients and any absences from work into account, too.

If the analysis is carried out from the perspective of the service provider, e.g. a hospital, it is enough to use hospital data. A social perspective, however, is broader than that. Nevertheless, analyses at hospital level (healthcare, provider) are not problem-free either, since there may be resources used that a hospital’s documentation does not specifically include as a resource, and, consequently, data on those may not be available. In establishing representativeness and generalizability one must proceed from the goal of the research, which may be providing support for local (hospital) or national decision-making. In the first case it is reasonable to use data from the institution, while in the latter it may be justified to use national registries, since those aggregate data represent an average state, come from many sources and do not depend on any local differences that may be considerable at times. The extent of the expected impact of a certain resource element on the final result determines the precision with which the given resource element has to be measured.

4.1.3. Assessing the value of the resources

In determining the values of the resources the resources used during health interventions are expressed in terms of money. First, the unit prices of the resources have to be determined. Very often, resources used in healthcare do not have prices formed under the circumstances of a transparent and perfectly competitive market. Many times fees and rates in healthcare do not represent the value of the given products correctly, but they are only a part of the financial funding system, whose goal is to reimburse providers of healthcare services for the input of resources used.

4.1.3.1. Cost or fee

The level of detail in costs calculation depends on the purpose of the analysis. If the goal of a health economic analysis is to get a global picture of the costs in a given area, a global costs calculation may be sufficient. In global costs calculation the process of the given intervention must be examined by breaking it down into larger components which their resource requirements (costs) need to be identified as in, for example, costs calculations based on homogeneous disease groups. For example, the basis of a costs calculation may be the support and funding provided by OEP at the levels of primary, outpatient and hospital care, or, in another approach, at the global levels of diagnostics, therapy and interventions, also based on OEP financing.

The advantage of global costs calculation is that it can be carried out fast, by using relatively few resources and the chances of the generalizability of the results of the analysis are greater. However, the price to be paid for the advantages is lower accuracy, since the 'actual' cost in this case may differ from what, e.g. the OEP pays to the provider in the framework of funding based on homogeneous disease groups.

The costs, however, are different not only from funding based on homogeneous disease groups but also from the fees set by healthcare providers. Providers may determine the fees to be paid at a lower level in the case of some services or some patients, while in the case of other services and groups of patients they may calculate fees exceeding the actuals costs. This costs calculation makes economic analyses considerably more difficult as both funding based on homogenous disease groups and the fees determined by providers are distorted approximations of the actual costs.

The other alternative is micro-costs-calculation, which allows the exact identification, measurement and expression in terms of money of various resources. This method is more labour-intensive but it provides a more precise picture of the relationships, characteristics and costs of individual activities. In micro-costs-calculation the process of an intervention must be broken down further to smaller units and resource inputs, identifying every activity and resource requirement of the intervention. For example, in global costs calculation hospital cost per patient day may be used as a unit of resource requirement. In the case of micro-costs-calculation this unit is examined and broken down into further constituents (medical care, care, diagnostic tests, medicines). However, the identification of resources is not problem-free in micro-costs-calculation. Calculations based on list prices are often misleading, since the unit price of a product (be it a medicine, instrument or technology) greatly depends on the

quantity ordered or other orders and any discounts granted. Further difficulties are caused, for example, in the case of medicines by the distorting effect of price-volume agreements, manufacturers' cash back offers and any other cost control methods. Moreover, such effects may manifest themselves in very different forms in the cases of various providers. Thus, reliable data are not easy to acquire by this method either.

4.1.3.2. Recommended prices/costs

In several countries, in order to facilitate unified and standardized costs calculation, the costs of the particular services are published besides the health economic and costs calculation guidelines. In the actual costs calculations these cost elements are used.

In Hungary such officially published data are not available; they are to be calculated by the specialist preparing the analysis. Such important costs are, for example:

- the cost of 1 visit by a GP , which can be calculated from the entire budget of a GP and the number of doctor-patient encounters (the cost per visit was HUF 1 475 in 2012),
- the cost of 1 visit by a specialist, calculable from data available generally or in the given field (the cost per outpatient care was HUF 1 642 in 2012)
- the cost of active and chronic in-patient care per day can also be calculated; in 2012 the cost of hospital care per day was HUF 17 181.
- the cost of travel/transportation by ambulance per 1 km or per case can also be calculated if the fares/rates are known (and, of course, if it is known how far patients travel on the average in order to use the given care, e.g. by questionnaire survey), in 2012, for example, the cost of transportation by ambulance per 1 km was HUF 888 and the average distance was 25 km.
- the prices of medicines, medical accessories and diagnostics are available on the OEP website,
- the costs (fees) of home care are also available in the case of services funded by social security,
- the cost per hour of 'another person's help' can be approximated in the following way: the value of average net wage per average working hour = HUF net wage/month/174 (the number of monthly working hours), while the number of hours actually spent can be determined by a research specifically designed for that purpose.

4.1.3.3. Costs related to the disease (disease burden)

In preparing decisions on health policy disease burden and disease cost examinations have become widely used. These are based on the assumption that the social burden established by the analysis (costs, decrease of quality of life, missed work and other consequences) appears as a benefit provided the problem is solved (preventing, curing the disease). The goal of costs calculation is often the quantification of the disease costs (disease burden). This allows the calculation of episode, (e.g. heart attack costs from falling ill till recovery), 30-day and annually (or longer if need be) costs of illnesses. It is always advisable to exactly specify in the case of what disease, what subgroup (age, gender, anamnesis, form of care), in what time range, from whose perspective (service provider, funder, society) and according to what methodology the costs calculation is made.

In many countries the disease burden data to be used in costs calculations are published and revised from time to time. As an example the episode or 12-month costs of heart attack or stroke, which could be prevented by a new drug therapy, can be mentioned here. If the goal is the cost-effectiveness analysis of such a new medicine, these are very important data, since these are the costs that can be prevented as a result of the therapy and taking these into account makes the cost-effectiveness more favourable.

Disease costs results can be found both in the Hungarian and the international literature, e.g.:

- heart attack, in the first year following the incident (direct cost) (Gulácsi et al., 2007)
- stroke (acute cerebrovascular accident) in the first year after the incident (active care) (Kárpáti et al., 2007)
- costs of medial femoral neck fractures in patients younger than 60 treated with osteosynthesis with screw or by implanting prosthesis (Sebestyén, 2004; Sebestyén et al., 2006; Sebestyén, 2009)
- rheumatoid arthritis (specific polyarthritis) (on the basis of a survey of patients without biological therapy) Péntek et al., 2007; Péntek et al., 2008; Brodszky et al., 2009; Péntek et al., 2011; Brodszky et al., 2014)
- arthritis psoriatica (psoriatic arthritis) (Brodszky et al., 2009)
- insulin-dependent diabetes (Brodszky et al., 2010)
- dementia (GPs' and specialists' patients) (Érsek et al., 2010)
- epilepsy (Péntek et al., 2013)

- Parkinson's disease (Tamás et al., 2014)
- schizophrenia (Péntek et al., 2012)
- sclerosis multiplex (Péntek et al., 2012)
- scleroderma (Minier, 2010)
- psoriasis (Balogh, 2014; Rencz, 2014)
- peripheral arterial disease (Balogh, 2013)

A good example for the above are hip fractures (femoral neck fractures) discussed in Chapter 5.3.3.1. and shown in Figure 5.2, where you could see that the cheaper solution financed by OEP causes significant added costs from the perspective of the patients, i.e. the society, due to missed work. (Sebestyén, 2004)

When using Hungarian and international literature sources one must also consider that various costs calculations are from various years, the populations of patients may be different, as well as the selection and inclusion criteria, the methodologies and the perspectives of costs calculation. That is why using such data requires utmost care.

Consequently, that may also mean that differences in figures do not necessarily represent actual differences. By themselves, differences are not informative either; it is advisable to see the variation of which cost element causes the difference. Among other things, it is because of this that the result of a costs calculation should be available broken down into 'relevant resource (cost) elements', 'the extent of the utilization of the identified resources' and 'the values of the resources'.

4.1.3.4. Taking transfer costs into account

Concerning the use of transfer costs (e.g. sick leave, disability pension) an internationally unified view prevails in costs calculation. Since social transfers do not reflect the actual productivity costs and/or production losses, it is usually not recommended to take social security benefits paid for diseases, disabilities or early deaths into account in health economic calculations. Nevertheless, if the objective of the health economic analysis is the examination of the impacts of various therapeutic possibilities on sick leave, they, of course, need to be considered. (Boncz, 2006)

4.1.3.5. Taking other costs into account

Other costs, for example, those of any remodelling of flats, costs due to changed lifestyles, diets and mobility may also be significant. Which costs need to be considered always depends on the given area and the objective. It cannot be formulated more precisely than by saying ‘all cost factors that might be important need to be considered’.

4.2. THE PERSPECTIVES OF COSTS CALCULATION

The selected perspective, i.e. the point of view from which the costs are studied, has a great significance in costs calculation. From the patient’s, the health insurance company or from the society’s view? Choosing a point of view is not only important from the aspect of what is reasonable to measure but also of how it is reasonable to measure the resources used. A costs calculation may be carried out from the perspective of the society, which allows a consideration of the entirety of the use of resources. That way all the costs can be surveyed regardless of whose budget they affect. Such a wide perspective allows the assessment whether a given type of health care should be introduced or not. If the economic analysis is carried out from another perspective, for example that of the service provider or the insurance company, the perspective of the analysis is narrower. It is important to stress that the chosen perspective has an important effect on all three main steps of costs calculation: the identification of the resources, the measurement of the resources and the determination of the values of the resources utilized, too.

Thus, different results can be reached depending on whether the investigation of the costs is done from the point of view of the service provider, the funder, the society, the tax payer or the patient. The indirect costs listed in Tables 1 and 2, whose volumes are considerable, are not ‘seen’, for example, by the service provider and the funder, since it is not they who incur them. On the other hand, the direct non-healthcare costs also visible in the tables are not hidden from the provider (e.g., the hospital) as they appear elsewhere.

4.3. CATEGORIES OF COSTS

The resources (costs) can be grouped according to cost types in the following way: direct healthcare costs, direct non-healthcare costs; and indirect costs.

4.3.1. Direct healthcare costs

Direct healthcare resources are those that are directly necessary for health interventions. These include, for example, laboratory costs, equipment, medication costs, doctors' salaries, visits and daily costs of hospital beds. In the case of equipment and instruments the costs of the whole life cycle must be considered: purchase price, maintenance, personnel, administrative, repairing, staff training and management costs and even the costs disposal. Even the determination of certain direct costs may often be difficult. In many cases it is also hard or impossible to establish the direct costs of devices, instruments and other equipment (they need to be estimated) as manufacturers/merchants calculate their prices based on the volume of an order. Thus, even the direct cost of the unit price of an item can vary. Very often the volume-dependent prices of medicines, medical accessories and other products and services mentioned above are not known because of the discounts, manufacturers' cash back offers and the deals made between the OEP and the given hospitals. In such cases list prices may be used or estimates have to be given, but it must be indicated in every case where a given unit price comes from or how a calculation was made.

4.3.2. Direct non-healthcare costs

These are the direct non-healthcare resources that are necessary for health interventions. This category includes, for example, the transportation and accommodation costs related to using health services as well as the costs of children's and patients' homecare and/or any flat/house remodelling (in the case of disabilities). It also includes the costs of special diets in the case of diseases.

Direct non-healthcare costs the time of those providing informal care and all other costs of informal care are categorized. Besides care by healthcare professionals funded by social security, family members, acquaintances, friends, volunteers and neighbours also plays a part in caring for patients in the form of informal care in a considerable part of the cases. Although in some of these cases these people do not get any reimbursement, their help still needs to be considered as cost from a social point of view without any doubt. During the time period when an 'other person' provides some service to a patient he/she could also do some paid

work, which is the basis of costs calculation in this case. The costs analysis of informal care could be especially important in the case of the group of patients where informal care often requires a lot of time, resulting in very high costs, in turn. The significance of informal care is rapidly growing all over the world. Formal healthcare is not able to provide full care to patients until they recover. Moreover, it is not possible even theoretically in the case of chronic diseases or statuses. In the case of problems and illnesses more and more patients turn to their family members, friends, acquaintances, neighbours or even Internet sites for advice and/or help. Patients do not stay in hospital until full recovery, but hospitals try to release them in a condition that allows full healing with the help of those providing informal care, as mentioned above. The costs of informal care may even reach 30-50 % of the full costs in some cases. The costs calculation for the costs of help by 'other persons' is extremely difficult in many cases, and may be the source of a lot of uncertainty and error. For example, if someone looks after his/her sick elderly family member or child in his/her home, he/she may spend 24 hours a day with the patient, but those 24 hours cannot be regarded as cost. Parents look after their healthy children too, and do other activities besides, as well, and they are really difficult to separate in real life circumstances. If help cannot be exactly defined either in the form of the activity or the time required for it, it is recommended that 8 hours daily should be the maximum taken into account during the costs calculation.

In the estimation of the costs of informal care (help 'by other persons') the following are the most common methods:

- **The method of markets costs:** allows the calculation of the expenses that the purchase of the given service (care, cleaning) costs in the market. These costs can be calculated in several ways, e.g. by price lists if the exact price list for the services is known. In such a case it is reasonable to know the demographic parameters of those providing the service as well as the exact structure of the activity and the time spent on it, too. It is simpler and closer to reality if the hourly cost of informal care is estimated on the basis of the average net income per hour in the given year. This value was HUF 832/hour in Hungary in 2012.

- **The method of benefit-sacrifice costs:** in this case the base of calculation is the income the provider of the informal service would get if he/she were doing paid work. It often poses a problem as those providing informal care are not of active age or they are housewives. There are several methodological possibilities; it is assumed that estimating the value of the average

minimum income per hour of the given year leads to results approximating reality. This value was HUF 369/hour in Hungary in 2009.

If help by 'other persons' is paid work, the actual amount paid is the cost.

The calculation of the costs of informal care greatly differs in individual countries, even in various disease areas. When making costs calculations the relevant literature of the given area needs to be studied, since the results of Hungarian calculations can only be interpreted if compared to the international literature. It is to be emphasised that in this area there is no universally accepted, standardized methodology for costs calculation either in Hungary or in the international literature; it is done by very many in many different ways. Consequently, it is very important also for this reason that the process of costs calculation should be described precisely and in detail, as without that the results could not be interpreted.

4.3.3. Indirect costs

Patient time is the evaluation and expression of paid and unpaid work and free time missed due to an illness in terms of money. For calculating the costs of a unit of time (e.g. 1 month) of missed work, however, an international consensus has been reached: it is advisable to calculate the average monthly gross income of the given year (average gross income plus taxes and contributions paid by the employer), the value of which was HUF 293 231 in Hungary. (<http://www.nettober.com/index.php?p=berkalkulator>)

The cost caused by changes in work productivity, productivity cost, represents the value of time the individual spends off work sick. Either the term 'direct costs' or 'indirect costs' were used. Productivity costs may amount to a significant sum of the total of costs related to the disease. The best-known example for that is the loss of (gross) income during incapacity. The importance of productivity cost varies greatly in the different areas of healthcare; there are areas where it is almost negligible, while in other cases its role is significant (e.g. in the case of rheumatoid arthritis 55%, arthritis psoriatica 44 %, dementia 45 %). Generally it may be said that the role of productivity costs can be considerable if reaching the desired output (health benefit) requires a long time, and if the patient stays away from work for a prolonged period, and/or a significant sum of the target population (or those providing informal care) belongs to the active age group. In healthcare the literature of productivity costs is mostly concerned with how time missed from work or free time in connection with illness can be assessed. The two most widely used, clearly distinct methods for the assessment of time

missed from work or free time are: the human capital approach and the friction costs approach.

The application of the two methods may lead to significantly different results in individual cases. Thus, it is recommended to calculate and publish the results reached by both methods. The difference of indirect costs calculated by the human capital and the friction cost methods may even be 10-40-fold in Hungary. (Boncz, 2005).

4.3.3.1. The human capital approach

The goal of the human capital approach is to determine the potential net results of individuals. For establishing net results usually average gross monthly incomes are used. In other words, the goal of the human capital method is the estimation of the loss of gross income due to illness or death. The costs incurred by family members and friends are not taken into account by this method.

The human capital approach regards the nature of human life to be the same as that of other economic goods. In the human capital approach the benefit-sacrifice costs method is used, i.e. the value of a given good, in this case human life, is to be determined by the financial loss an individual would suffer by losing the given good. The loss is proportional to the total of the gross income that would be attainable with the help of the good during a given period of time. The human capital approach examines three areas in detail: the assessment of missed paid work (due to death or illness), the assessment of the change in the time of unpaid work and the assessment of the change in free time.

- Assessing missed paid work

Great gross income includes the additional costs of employing labour, i.e. pension and other contributions paid by employers for employees. According to the human capital approach the value of time spent away from paid work due to illness or using health services is measured by the value of gross income.

- The assessment of the change in free time

Changes in free time due to illnesses are also of value to individuals. This aspect rarely appears explicitly in the assessment of changes in productivity in the human resource

approach. The basic principle of the method prescribes how this factor has to be taken into account. If it is assumed that an individual's time may be divided into paid working time and free time, free time is the benefit-sacrifice cost of the working time that the individual sacrifices for the sake of paid work, and which may be regarded as a wage/salary. In cost-effectiveness analyses it is also reasonable to consider any changes in free time (and its value) during the calculation of health benefits achievable by treating diseases.

4.3.3.2. The friction cost approach

The friction cost method is a modified version of the human capital method, the purpose of which is the calculation of the actual, real losses. While the human capital method takes the loss into account from the beginning of the illness or the time of death until the end of the period that could have been spent at work, the method of friction costs limits the period examined to the friction period, which is normally 6 months. That refers to the period necessary for finding suitable replacement for the missing labour.

Another fundamental difference between the two methods is that the method of friction costs assumes the following:

- the individual is able to make up for work missed due to his/her illness in the case of a shorter absence after his/her return to work, or perhaps
- the individual's work is taken over by an internal working group kept for this specific purpose, or
- in the case of work that is not urgent, the given job may be cancelled, and
 - in the case of a prolonged period of illness the employer can employ an unemployed colleague to replace the individual on sick leave.

The assessment of the value of free time is not among the objectives of the friction cost method.

4.4. CASE STUDY FOR THE CHALLENGES OCCURRING IN COSTS CALCULATION

Cystic fibrosis (CF, formerly also known as mucoviscidosis) is a rare, hereditary, chronic, progressive disease. Its frequency in Hungary is 1:4000 among live births.

4.4.1. The size of the therapeutic target group

According to the patient registry of the European Cystic Fibrosis Society (ECFS) there were 557 patients registered in Hungary in 2010 with an estimated coverage of the actual number of patients by the registry of 90%.

1. **question:** How many new cases are expected each year?

Answer: According to the data of the Hungarian Central Statistical Office (<http://www.ksh.hu>) the number of live births showed the following changes between 2009 and 2013 (Table 9)

Table 9 Number of live births 2009-2013

Year	Number of live births
2009	99 442
2010	96 442
2011	90 335
2012	90 269
2013	88 689

In the past 5 years there were 90,757 live births on average in a year. Considering the ratio of 1:4000 CF/live births, that means 23 new CF patients. (1 new CF /4000 live births) This is shown in Table 10.

Table 10 Number of live births and the estimated number of new CF patients 2009.013

Year	Number of live births	Estimated number of new CF patients
2009	99 442	24
2010	96 442	23
2011	90 335	33
2012	90 269	23
2013	88 689	22

2. **question:** According to the registry data how many CF patients live in Hungary?

Answer: If 557 CF patients are 90% of all CF patients, the total of CF patients in Hungary is 619 patients.

However, concerning each cost element one cannot calculate the fact that every patient uses them (e.g. not every patient takes certain medicines, patients of different ages and in different stages use different medical accessories, etc.). That is why prevalence data only provide a starting point for further estimates in most cases.

4.4.2. Identifying cost elements

The identification of the cost elements is facilitated by the protocol of the treatment of the the CF disease: “The professional protocol of cystic fibrosis of the Ministry of Health”.

https://kollegium.gyemszi.hu/conf/upload/oldiranyelvek/GYERM_cystas%20fibrosisrol_mod0_v0.pdf)

Take as an example the part about the treatment of the so-called *Pseudomonas aeruginosa* infection, an important complication.

Treatment of early *Pseudomonas aeruginosa* infections

“For the treatment of early *Pseudomonas aeruginosa* infections and the later quality of life and survival of CF patients the age at the first

P. aeruginosa infection, the intermittent colonization, and then the chronic infection (presence of anti *pseudomonas* antibodies) are of decisive importance.

Infection by the *P.aeruginosa* strain, especially after the development of the mucoid strain, leads to an accelerating progression of the lung process. The eradication of strains adapted to the respiratory epithelium of CF patients’ is difficult.

In the case of the first *P. aeruginosa* positive nasopharyngeal swab culture the repetition of the sample taking and the establishment of the antibody titer of *P. aeruginosa* /it correlates well with the invasiveness of the pathogen/ is justified. Treatment: 3-week TOBI or Colistin inhalation and per os ciprofloxacin. In the case of young children immediate targeted intravenous treatment is to be applied. **Recommendation “A”**

The prolongation of the combined treatment to three months increases the recurrence from 9 months to 18 months. Recommendation B.

In the case of the difficulty of per os drug delivery or in the case of an age obstacle, inhalation can also be applied with success in a monotherapy. Recommendation C.

TOBI inhalation of an effectiveness equal to that of colistin inhalation. **Recommendation “A”**

In the case of no success by TOBI or colistin treatment and/or the occurrence of infectious symptoms, besides continuing the inhalation, a two-week ceftazidime, tobramycin intravenous treatment is justified. It is worth continuing the inhalation for three months after the end of the intravenous treatment, even if cultures have become negative in the meanwhile, and the anti *P. aeruginosa* antibody titer is normal. **Recommendation “C”**

Once a patient’s *P. aeruginosa* was positive, it is justified to carry out microbiological cultures every month, especially during periods of respiratory infections. Recommendation B 16

If from a CF patient *P aeruginosa* can be isolated again, the same procedure has to be followed as during the first positive finding, but a three-month TOBI or colistin inhalation is also to be considered either with or without per os ciprofloxacin. **Recommendation “C”**

In the case of further positive results the TOBI or colistin, ciprofloxacin treatment is to be continued. The examination of the *P. aeruginosa* genom and the antibody titer may help with the separation of reinfection and unsuccessful eradication. **Recommendation “B”**

In the case of unsuccessful eradication a combined, targeted intravenous antibiotic treatment is recommended besides inhalation. Recommendation C.

In the case of an unsuccessful intravenous treatment the continuation of the inhalation and a regular, three-monthly intravenous therapy is justified. **Recommendation “C”**

At the beginning of every respiratory infection of patients with recurring P. aeruginosa positivity a two-week per os ciprofloxacin treatment is to be started. **Recommendation “A”**

Every chronic P. aeruginosa positive CF patient is to receive regular inhalation antibiotic treatments. Recommendation A16

The primary medicine of choice is colistin. **Recommendation “B”**

In the case of unsuccessful colistin inhalation or difficulties in toleration TOBI inhalation is justified. **Recommendation “C”**

3. **question:** The administration of which medicines is mentioned in the professional protocol?

Answer: ciprofloxacin, colistin, TOBI

With the help of the professional protocol 3 potential cost items (3 therapies) have been identified in CF.

4. **question:** Search the drug database of the National Institute of Pharmacy for these three recommended therapies. What drugs do you find?

(<http://www.ogyi.hu> Drug information ... Drug database)


Answer (data for 21/10/2014)

The database contains 46 products containing Ciprofloxacin as the active substance, of which, however, some have been deleted from the registry and marked (TT). (Figure 8)

Figure 8 Search for Ciprofloxacin products in the drug database of the National Institute of Pharmacy (excerpt)





Gyógyszer-adatbázis

[Használati útmutató a gyógyszeradatbázishoz](#)
[Rövidítések](#)

Szabadszavas keresés 

Gyógyszer neve Forgalomba hozatali eng. jogosultja

Hatóanyag ATC-kód Nyilvántartási szám Kiadhatóság












Engedélyezés dátuma  -tól  -ig Törlés dátuma  -tól  -ig

Rendezési szempont

a keresés indítása **a kereső alaphelyzetbe állítása**

Az adatbázis utolsó frissítésének dátuma: 2014. 10. 07

1 - 20. a(z) 46 találatból

Gyógyszer neve	Készítés	Hatóanyag	ATC-kód	Forgalomba hozatali eng. jogosultja	Kiadhatóság	Státusz	
CIFLOXIN 100 mg/50 ml oldatos infúzió	5x injekciós üvegben	ciprofloxacin	J01MA02	Sandoz Hungária Kft.	I	TT	
CIFLOXIN 200 mg/100 ml oldatos infúzió	5x injekciós üvegben	ciprofloxacin	J01MA02	Sandoz Hungária Kft.	I	TT	
CIFLOXIN 250 mg filmtabletta	10x buboréksomagolásban	ciprofloxacin	J01MA02	Sandoz Hungária Kft.	V	TK	
CIFLOXIN 400 mg/200 ml oldatos infúzió	5x injekciós üvegben	ciprofloxacin	J01MA02	Sandoz Hungária Kft.	I	TT	
CIFLOXIN 500 mg filmtabletta	10x buboréksomagolásban	ciprofloxacin	J01MA02	Sandoz Hungária Kft.	V	TK	
CIFRAN 250 mg filmtabletta	10x buboréksomagolásban , 20x buboréksomagolásban	ciprofloxacin	J01MA02	Ranbaxy UK Ltd.	V	TK	
CIFRAN 500 mg filmtabletta	10x buboréksomagolásban , 20x buboréksomagolásban	ciprofloxacin	J01MA02	Ranbaxy UK Ltd.	V	TK	
CIFRAN 500 mg filmtabletta	10x	ciprofloxacin	J01MA02	EU Pharma Kft.	V	PI	
CIFRAN 750 mg filmtabletta	10x buboréksomagolásban , 20x buboréksomagolásban	ciprofloxacin	J01MA02	Ranbaxy UK Ltd.	V	TK	
CILOXAN 3 mg/ml oldatos szem- és fülcsepp	1x5 ml tartályban LDPE	ciprofloxacin	S03AA07	Alcon Hungária Kft.	V	TK	
CIPLOX 250 mg filmtabletta	10x buboréksomagolásban	ciprofloxacin	J01MA02	IBMED Kft.	V	TK	

The active substance **colistin** is also searchable in the OGYI drug database but it delivers no hits. (Figure 9)

Figure 9 Full text search for “colistin”, listed in the professional protocol, in the drug database of the National Institute of Pharmacy



Gyógyszer-adatbázis

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Szabadszavas keresés 

Gyógyszer neve Forgalomba hozatali eng. jogosultja

Hatóanyag ATC-kód Nyilvántartási szám Kiadhatóság

Engedélyezés dátuma  -tól  -ig Törlés dátuma  -tól  -ig

Rendezési szempont

Az adatbázis utolsó frissítésének dátuma: 2014.10.07

A keresett készítmény nem található adatbázisunkban.

It may occur to one that there is a spelling error in the background of the problem, but that is not the case. If one looks for the active substance **colistin** in the OGYI drug database, it is listed, but there are not any products containing that active substance. (Figure 10)

Figure 10 Search for the active substance Colistin in the drug database of the National Institute of Pharmacy

The screenshot shows the search interface of the National Institute of Pharmacy drug database. The search results list the following active substances:

- clotrimazole
- clove oil
- clozapine
- coal tar
- cod-liver oil (type A)
- cod-liver oil (type B)
- codeine
- coenzym Q10
- colchicine
- colesevelam
- colistimethate sodium
- colistin** (highlighted)
- collagenase
- Comb. Vaccine
- conestat alfa
- Copper
- corifollitropin alfa
- Couch grass rhizome
- crataegus glycosides
- crizotinib

Below the list, there are several input fields and buttons:

- Engedélyezés dátuma: [] -tól [] -ig
- Törlés dátuma: [] -tól [] -ig
- Rendezési szempont: Gyógyszer neve
- Buttons: **a keresés indítása** and **a kereső alaphelyzetbe állítása**


At the bottom, it states: "Az adatbázis utolsó frissítésének dátuma: 2014.10.07" and "A keresett készítmény nem található adatbázisunkban."

Thus, searching for the “**colistin**” therapy mentioned in the professional protocol has not been successful in the OGYI drug database. However, if one searches for the active substance **colistimethate sodium** just above that, two hits are displayed with the manufacturer’s drug name **COLOMYCIN**.

Figure 11 Search for the active substance Colistimethate sodium in the drug database of the National Institute of Pharmacy

Gyógyszer-adatbázis

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Szabadszavas keresés 

Gyógyszer neve: - válasszon a listából -
 Forgalomba hozatali eng. jogosultja: - válasszon a listából -

Hatóanyag: colistimethate sodium
 ATC-kód:
 Nyilvántartási szám:
 Kiadhatóság: - válasszon a listából -



Engedélyezés dátuma: -től -ig
 Törlés dátuma: -től -ig

Rendezési szempont: Gyógyszer neve

a keresés indítása **a kereső alaphelyzetbe állítása**

Az adatbázis utolsó frissítésének dátuma: 2014.10.07

1 - 2. a(z) 2 találatból

Gyógyszer neve	Ízserelés	Hatóanyag	ATC-kód	Forgalomba hozatali eng. jogosultja	Kiadhatóság	Státusz
COLOMYCIN 1 000 000 NE por oldatos injekcióhoz , infúzióhoz vagy inhalációs oldathoz	10x injekciós üvegben , 60x	colistimethate sodium	J01XB01	Forest Laboratories UK Ltd. Sz	TK	
COLOMYCIN 2 000 000 NE por oldatos injekcióhoz , infúzióhoz vagy inhalációs oldathoz	10x injekciós üvegben	colistimethate sodium	J01XB01	Forest Laboratories UK Ltd. Sz	TK	

[eredmény megnyitása excelben](#)

Naturally, the question arises as to whether **colistimethate sodium** is the same as **colistin**, mentioned in the professional protocol? To find that out, first the description of the application of the drug needs to be seen (the red arrows on the right of the picture lead one to the detailed page presenting the drug, then the icon marked SPC contains the product information). There you can see that the active substance of the drug Colomycin is **colistimethate sodium** and its indication is “... the inhalation treatment of lung infections caused by Pseudomonas aeruginosa in cystic fibrosis (CF)”.

It may be assumed that **colistimethate sodium** is the same as **colistin** in the professional protocol, but it is worth consulting a specialist knowledgeable about CF or the authors of the protocol.

Searching the drug database for the third substance called “**TOBI**” in the protocol delivers 3 hits, one of which has been deleted from the registry (TT). It can also be seen that “**TOBI**” is the manufacturer’s name for the drug, Its active substance is **tobramycin**, which is written as **tobramicin** in the application description of the drug.

To sum it up, the professional protocol in its therapeutic recommendation - after making comparisons with the drug database of OGYI - lists the name of an active substance (ciprofloxacin), a name resembling the name of an active substance (colistin) and a manufacturer’s name of a product (TOBI). The picture is further complicated by the differing ways of writing the names of the active substances on the OGYI website and the application descriptions available there.

4.4.3. Measurement of cost elements

The consumption of drugs can be measured *retrospectively* by using questionnaires, where the patients are asked what medicines they took in the previous month and in what dosage. If one wants to expand the data taken for 1 month to a period of one year, a good approximation is received in the case of drugs taken continuously if one month’s drug costs are multiplied by 12 months. The measurement can be done *prospectively* too, with information from the patient records and/or the doctor’s documentation kept from the beginning of the illness.

From the professional protocol it can be seen that in CF it greatly varies how long and how CF patients receive, e.g. ciprofloxacin products. That is why it is very likely that the retrospective recording of data or expanding the current therapy to 1 year only yields approximate estimates.

4.4.4. Assessing the value of cost elements

For costs calculation, however, drug prices are needed too.

5. **question:** What are the prices of the 3 drug therapies: ciprofloxacin, **colistin (colistimethate sodium)** or **TOBI (tobramycin or tobramicin)**, recommended in the professional protocol?

Search the professional sites of the National Health Insurance Fund of Hungary (OEP).

(<http://www.oep.hu> Szakmai oldalak... Gyógyszer... Gyógyszerek, gyógyszerpiac ...

Publikus gyógyszer-törzs... Publikus gyógyszer-törzs – végleges ... Lakossági tájékoztató)

Answer (data for 21/10/2014):

In the Public Drug Registry's Public Information Excel file one finds 25 drugs with the active substance **Ciprofloxacin**. (Table 11)

Table 11 Products containing Ciprofloxacin in the public information file of the public drug registry of the National Health Insurance Fund of Hungary (21/10/2014 - selected data, not all information is shown in the present table)

Készítmény megnevezése	Kiszerezési egység	ATC-kód	Hatóanyag
CIFLOXIN 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIFLOXIN 500 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIFRAN 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIFRAN 500 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPLOX 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPLOX 500 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPRINOL 2 MG/ML OLDATOS INFÚZIÓ	1x100ml infúziós üvegben	J01MA02	ciprofloxacin
CIPRINOL 2 MG/ML OLDATOS INFÚZIÓ	1x200ml infúziós üvegben	J01MA02	ciprofloxacin
CIPRINOL 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPRINOL 500 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPRINOL 750 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPROFLOXACIN 1A PHARMA 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPROFLOXACIN 1A PHARMA 500 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CIPROFLOXACIN KABI 200 MG/100 ML OLDATOS INFÚZIÓ	1x infúziós zsákban	J01MA02	ciprofloxacin
CIPROFLOXACIN KABI 200 MG/100 ML OLDATOS INFÚZIÓ	10x infúziós zsákban	J01MA02	ciprofloxacin
CIPROFLOXACIN KABI 400 MG/200 ML OLDATOS INFÚZIÓ	1x infúziós zsákban	J01MA02	ciprofloxacin
CIPROFLOXACIN KABI 400 MG/200 ML OLDATOS INFÚZIÓ	10x infúziós zsákban	J01MA02	ciprofloxacin
CIPROFLOXACIN-HUMAN 2 MG/ML OLDATOS INFÚZIÓ	1x100ml infúziós zsákban	J01MA02	ciprofloxacin
CIPROFLOXACIN-HUMAN 2 MG/ML OLDATOS INFÚZIÓ	1x200ml infúziós zsákban	J01MA02	ciprofloxacin
CIPROFLOXACIN-HUMAN 250 MG FILMTABLETTA	10x átlátszó buborékcsomagolásban	J01MA02	ciprofloxacin
CIPROFLOXACIN-HUMAN 500 MG FILMTABLETTA	10x átlátszó buborékcsomagolásban	J01MA02	ciprofloxacin
CIPROFLOXACIN-HUMAN 750 MG FILMTABLETTA	10x átlátszó buborékcsomagolásban	J01MA02	ciprofloxacin
CIPROLEN 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CYDONIN 250 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin
CYDONIN 500 MG FILMTABLETTA	10xbuborékcsomagolásban	J01MA02	ciprofloxacin

Source: OEP Public Drug Registry, 21/10/2014

With the active substance called **colistin** one drug has been found (product's name **COLOMYCIN**), in two different types of packaging. Searching for the the active substance **colisthimethate sodium** has produced no hits.

Tobramicin has delivered two hits (the manufacturers' names for the products: **TOBI, BRAMITOB**), searching for **tobramycin** has also produced 2 hits (product names: **TOBREX, BRULAMYCIN**).

In the case of ciprofloxacin and colistin the active substances are obvious, TOBI should be discussed with an expert (may only the drug TOBI be recommended as the professional protocol suggests or may the other medicines also be considered; does the difference in spelling between tobramycin and tobramicin matter?).

Determining the value of the cost element also poses several challenges.

Taking ciprofloxacin for example, the following questions arise among others:

- Is it known exactly which product the patient took in the period examined?
- If not, the price of which drug with the same active substance and packaging should one calculate? Should the lowest price be considered or the drug that sold the best according to the drug consumption data of OEP? Or should an average price be used?

The prices and subsidization of products with the active substance ciprofloxacin in the OEP website are shown in Table 12.

Table 12 Products, packages and subsidization

Készítmény megnevezése	Kiszerelési egység	ATC-kód	Hatóanyag	Terápiás napok száma (DOT)	Termelői ár (Ft)	Nagykereskedelmi ár (Ft)	Bruttó fogyasztói ár (Ft)	Napi terápiás költség (Ft)	Normatív támogatásra vonatkozó			Kiemelt támogatásra vonatkozó paraméterek				Közgyógyon kiváltható-e		
									Normatív támogatás i technika	Normatív támogatás i kategória (%)	Normatív támogatás i összeg (Ft)	Térítési díj normatív támogatás esetén (Ft)	Kiemelt támogatás i technika	Kiemelt támogatás i kategória (%)	Kiemelt támogatás i összeg (Ft)		Térítési díj kiemelt támogatás esetén (Ft)	Vonatkozó indikációs pont (Eü. pont)
CIFLOXIN 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	445	480,6	641	256,4	NOMIN	25	160	481	NOMIN	100	341	300	9/a	Igen
CIFLOXIN 500 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	5	731	778,52	1006	201,2	HFIX	25	246	760	HFIX	100	684	322	9/a	Igen
CIFRAN 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	437	471,96	629	251,6	NOMIN	25	157	472	NOMIN	100	329	300	9/a	Igen
CIFRAN 500 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	5	804	856,26	1106	221,2	HFIX	25	246	860	HFIX	100	684	422	9/a	Igen
CIPLOX 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	419	452,52	604	241,6	NOMIN	25	151	453	NOMIN	100	304	300	9/a	Igen
CIPLOX 500 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	5	735	782,78	1011	202,2	HFIX	25	246	765	HFIX	100	684	327	9/a	Igen
CIPRINOL 2 MG/ML OLDATOS INFÚZIÓ	1x100ml infúziós üvegben	J01MA02	ciprofloxacín	0,4	1064	1129	1458	0	NOMIN	0	0	1458		0	0	1458		Nem
CIPRINOL 2 MG/ML OLDATOS INFÚZIÓ	1x200ml infúziós üvegben	J01MA02	ciprofloxacín	0,8	1575	1653,75	2099	0	NOMIN	0	0	2099		0	0	2099		Nem
CIPRINOL 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	447	482,76	644	257,6	NOMIN	25	161	483	NOMIN	100	344	300	9/a	Igen
CIPRINOL 500 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	5	731	778,52	1006	201,2	HFIX	25	246	760	HFIX	100	684	322	9/a	Igen
CIPRINOL 750 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	7,5	1878	1971,9	2484	331,2	NOMIN	25	621	1863		0	0	2484		Igen
CIPROFLOXACIN 1A PHARMA 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	417	450,36	601	240,4	NOMIN	25	150	451	NOMIN	100	301	300	9/a	Igen
CIPROFLOXACIN 1A PHARMA 500 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	5	715	761,48	984	196,8	HFIX	25	246	738	HFIX	100	684	300	9/a	Igen
CIPROFLOXACIN KABI 200 MG/100 ML OLDATOS INFÚZIÓ	1xinfúziós zsákban	J01MA02	ciprofloxacín	0,4	1500	1575	2016	5040	NOMIN	0	0	2016		0	0	2016		Nem
CIPROFLOXACIN KABI 200 MG/100 ML OLDATOS INFÚZIÓ	10xinfúziós zsákban	J01MA02	ciprofloxacín	4	15000	15660	17483	4370,75	NOMIN	0	0	17483		0	0	17483		Nem
CIPROFLOXACIN KABI 400 MG/200 ML OLDATOS INFÚZIÓ	1xinfúziós zsákban	J01MA02	ciprofloxacín	0,8	3000	3132	3946	4932,5	NOMIN	0	0	3946		0	0	3946		Nem
CIPROFLOXACIN KABI 400 MG/200 ML OLDATOS INFÚZIÓ	10xinfúziós zsákban	J01MA02	ciprofloxacín	8	30000	31320	33926	4240,75	NOMIN	0	0	33926		0	0	33926		Nem
CIPROFLOXACIN-HUMAN 2 MG/ML OLDATOS INFÚZIÓ	1x100ml infúziós zsákban	J01MA02	ciprofloxacín	0,4	2480	2589,12	3262	8155	NOMIN	0	0	3262		0	0	3262		Nem
CIPROFLOXACIN-HUMAN 2 MG/ML OLDATOS INFÚZIÓ	1x200ml infúziós zsákban	J01MA02	ciprofloxacín	0,8	4880	5094,72	6313	7891,25	NOMIN	0	0	6313		0	0	6313		Nem
CIPROFLOXACIN-HUMAN 250 MG FILMTABLETTA	10xátlátszó buboréksomagolásban	J01MA02	ciprofloxacín	2,5	419	452,52	604	241,6	NOMIN	25	151	453	NOMIN	100	304	300	9/a	Igen
CIPROFLOXACIN-HUMAN 500 MG FILMTABLETTA	10xátlátszó buboréksomagolásban	J01MA02	ciprofloxacín	5	731	778,52	1006	201,2	HFIX	25	246	760	HFIX	100	684	322	9/a	Igen
CIPROFLOXACIN-HUMAN 750 MG FILMTABLETTA	10xátlátszó buboréksomagolásban	J01MA02	ciprofloxacín	7,5	1859	1951,95	2459	327,87	NOMIN	25	615	1844		0	0	2459		Igen
CIPROLEN 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	550	590	762	304,8	NOMIN	25	191	571	NOMIN	100	462	300	9/a	Igen
CYDONIN 250 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	2,5	557	597	771	308,4	NOMIN	25	193	578	NOMIN	100	471	300	9/a	Igen
CYDONIN 500 MG FILMTABLETTA	10xbuboréksomagolásban	J01MA02	ciprofloxacín	5	908	967,02	1248	249,6	HFIX	25	209	1039	HFIX	100	581	662	9/a	Nem

Take the products with the active substance ciprofloxacin in 500mg tablets 10x packaging as an example (Table 13).

Table 13 500mg ciprofloxacin, 10-tablet packaging:

Medicine	Price (HUF/packet)
CIFLOXIN	1006
CIFRAN	1106
CIPLOX	1011
CIPRINOL	1006
CIPROFLOXACIN-HUMAN	1006
CYDONIN	1248

It may be a decisive factor, depending from whose perspective the costs calculation is carried out. From the point of view of the society the full drug price has to be calculated. That is why the gross selling prices are shown above.

In the case of normative subsidization the subsidization by the social security (TB cost) is shown in Table 14.

Table 14 500mg ciprofloxacin, 10-tablet packaging:

Medicine	Price (HUF/packet)	Subsidization (TB), HUF/packet
CIFLOXIN	1006	246
CIFRAN	1106	246
CIPLOX	1011	246
CIPRINOL	1006	246
CIPROFLOXACIN- HUMAN	1006	246
CYDONIN	1248	209

Thus, the amount payable by the patient varies between HUF 738 and 1039/packet.

In cystic fibrosis, however, all 6 listed products can be given with special subsidization (TB subsidization 100%) depending on indication. In this case the social security's and the patient's expenses are as follows (Table 15).

Table 15 500mg ciprofloxacin, 10-tablet packaging:

Medicine	TB subsidization	Patient's expenses
CIFLOXIN	684	322
CIFRAN	684	422
CIPLOX	684	327
CIPRINOL	684	322
CIPROFLOXACIN- HUMAN	684	322
CYDONIN	581	667

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5. QUALITY OF LIFE RESEARCH (M. PÉNTEK)

“I’d boast to everyone I see, How greatly life is treating me.”

(Attila József: Dear Jocó)

In human life two points are certain: every individual is born once and he/she has to die once. There may be some good and bad times, but time goes by nevertheless. If in connection with human life only its content were regarded, every life of the same length would be the same. It is, obviously, not like that. The difference is in the quality of the time lived.

How people perceive the quality of their lives depends on many factors. It is not the same if one has enough money, enough food and drink he/she can buy, or what his/her living conditions, family, workplace, cultural and political environment, etc. are like. Health and illnesses play an especially important role in the quality of human life.

In assessing quality of life it must also be considered that people are not the same and they change, and their needs may change over time, too. Dear reader, you might have seen people absolutely happy about a tiny one-bedroom flat, while someone else felt miserable that that was all he/she could afford. It is not the same either whether that person had had a flat before or he/she had to move to the one-bedroom flat from a detached house. Some of those moving from the larger to the smaller place may feel sad about having to live in a little bedsit, while others may be happy because it had been difficult for them to maintain the big house. It does also happen that someone who used to be very happy about the small flat he/she managed to get starts to feel bad in there and would like to have a larger and nicer one.

Similarly, people may also experience health and illness in different ways. It is great when the painful headache is over, but later on one is not necessarily happy every moment that he/she does not have a headache. And someone who has never had one cannot even imagine what it must be like.

Although individual perspectives and the perceptions of life situations may be very different, it is obvious that a year of one’s life spent in good quality is more valuable than one spent in bad quality. Regarding health and healing, it is worth performing interventions that do not lengthen lives but make them better. On the other hand, there is need for methods meeting

scientific requirements which make changes in the quality of life reliably measured. To measure and evaluate “*How greatly life is treating me.*”

This chapter discusses the basic issues of health-related quality of life (HRQoL) research. The chapter draws on some of our earlier publications and book chapters on the topic [1-3]. It is indispensable as the introduction of the basic concepts and methods, which have not changed at all or only slightly over time, cannot be left out of the volume. The fresh examples, however, will - hopefully - make the chapter interesting and provide a different perspective.

5.1. THE BASIC CONCEPTS OF QUALITY OF LIFE RESEARCH

According to the definition of the World Health Organisation (WHO) “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” [4]. For the concept of health-related quality of life (hereafter: quality of life) there is no universal definition [5]. It is generally accepted that it is a multidimensional, subjective concept, which includes the effects of illnesses and any consequential therapies seen from the individual’s perspective.

The goal of health interventions is to restore the individual’s health-related well-being (and/or to prevent deterioration). In order to evaluate that, however, changes in the patient’s quality of life also need to be considered besides the conventional measures (e.g. survival). While many conventional medical outcomes can be measured by instruments (e.g. tumour size), about the changes in one’s quality of life the individual him-/herself can give information, which guarantees evaluation according to his/her subjective judgement.

5.2. HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRES

For the investigation of health-related quality of life mostly self-administered questionnaires have become common as they are easy to standardize. Quality of life questionnaires may be grouped according to the area of their use (generic and disease specific questionnaires). Another classification is based on whether the questionnaire expresses the result by a cumulative value, a so-called *index*, or by separate values for health dimensions, thus drawing a *profile* of the individual’s condition.

5.2.1. General health status measures

General questionnaires focus on those dimensions of health that are significant regardless of the specific character of any disease hidden in the background. Good examples for these are pain, mobility and social involvement. Limitations in these areas are important aspects of the quality of life. The advantage of general questionnaires is that they can be used in various diseases allowing their comparison. Typically, these questionnaires are far more common, they provide more data, they are used more and there is more experience of them. That is the reason why data from general quality of life questionnaires are more likely to be comparable to the average data of the population or the measurements of other countries. At the same time, a disadvantage, due to the general nature, is that less sensitive methods emphasise certain dimensions too much or too little. Thus, their application in comparative clinical trials is only recommended if the change in the quality of life is expected to be great or the general questionnaire used measures the area of the quality of life critical for the patient group to be examined to a sufficient depth.

The Short Form-36 (SF-36) is a general health status questionnaire often used as a secondary endpoint in clinical trials. (<http://www.sf-36.org>) It has been used for surveys among the Hungarian population too. So, population norms are available [6]. The questionnaire consists of 36 questions and provides calculable values for eight areas of health on the basis of the answers. The physical and mental areas can be united into one value each. The survey of the eight dimensions point out the problem areas, and it provides a *profile* of the patient's health status. The scores of the questionnaire range from 0 to 100, where a higher score indicates a better status. It is available in several languages.

Another common general questionnaire is the EQ-5D, which consists of two parts, a descriptive one and one measuring health. (<http://www.euroqol.org>) The descriptive part examines five dimensions of health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), where respondents have to mark the level of their problems in the given areas. The questionnaire has a 3-level response version (EQ-5D-3L), and a new version offering answers at 5 levels, which is more sensitive and capable of indicating slighter changes due to the more detailed response choices, has been developed in the past few years (EQ-5D-5L). The second part of the questionnaire is the one measuring health (EQ VAS), a 0-100 scale, the two extreme ends of which represent the best and worst health statuses possible. Respondent have to indicate how they feel on the day of the survey.

The EQ-5D questionnaire is very widely used; it has been validated for several languages and countries. It has also been used for population surveys in Hungary [7]. Thus, EQ-5D norms can be compared within a country and internationally too.

The Hungarian population survey carried out with the EQ-5D questionnaire showed that with age the proportion of people living with health problems increases in all the five dimensions of the EQ-5D. That means that the older you get, the worse your health becomes, and the deterioration is measurable. (Figure 7) In the various areas of health, however, the proportions of people reporting problems varies. Among young adults up to the age of 40 self-care problems, difficulties in mobility or in usual activities are negligible. At the same time, in the same age group quite a few people have some or extreme pain/discomfort or are anxious/depressed. Over the age of 40 the most common problems occurring in every age group occur in the pain/discomfort dimension; after 70 the curve flattens out. In the mobility, self-care, usual activities dimensions the proportion of those reporting problems grows further also in the oldest age groups, just like in the area of emotions.

Y: Percentage of people reporting some or extreme problems %

X: Age group (year)

Jelmagyarázat: mobility, self-care, usual activities, pain/discomfort, anxiety/depression

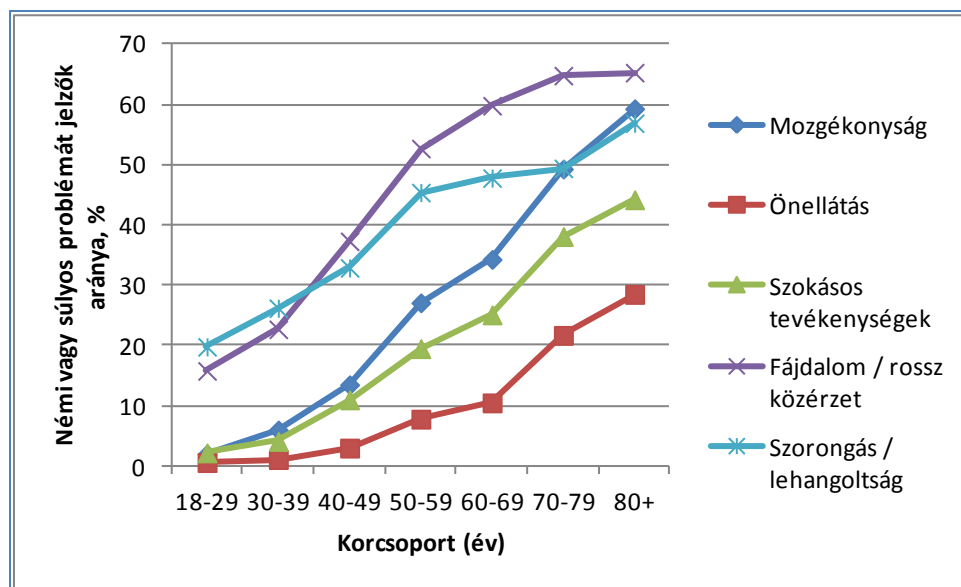


Figure 7 The proportions of people reporting some or extreme problems in the dimensions of the EQ-5D questionnaire in the average Hungarian population

Source: [7] (figure by author)

From the descriptive part of the EQ-5D a so-called *index* value, the details of which are presented in chapter 5.3.2, can be calculated. In Figure 2 it is visible from the differences of the EQ-5D values of women and men that health status deteriorates in both sexes with age, but men's average EQ-5D values are better than those of women in every age group. The EQ VAS measurement produced smaller differences between the two genders (and values were slightly lower than the EQ-5D index, the reasons for which are discussed in Chapter 5.3.1). It is known from the surveys of the Hungarian Central Statistical Office (KSH) that women's life expectancy is higher than that of men, but their health status is worse according to the EQ-5D index. (Figure 8)

Y: EQ-5D index / EQ VAS value, average

X: Age group (year)

Jelmagyarázat: EQ-5D index, male; EQ-5D index, female; EQ VAS*, male; EQ VAS*, female

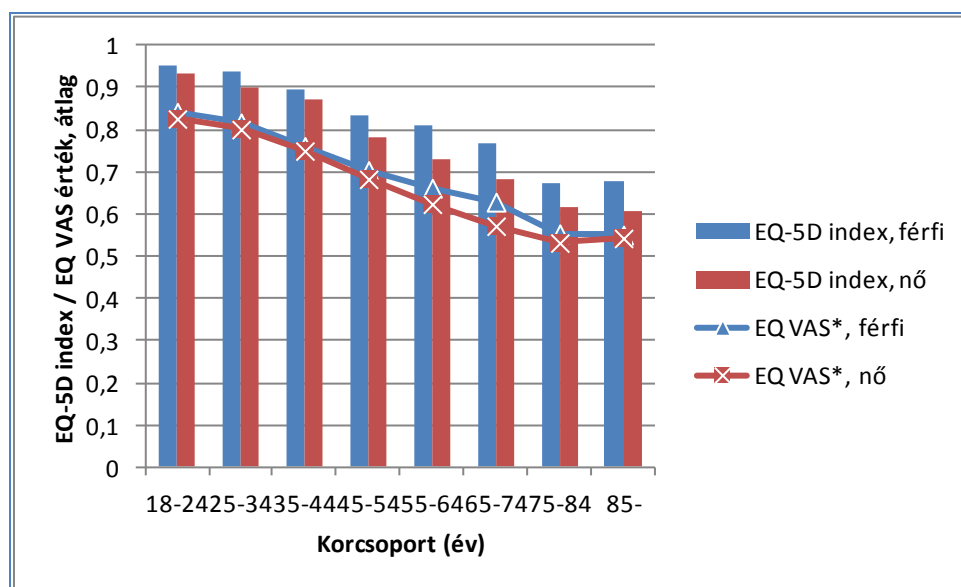


Figure 8 Average EQ-5D index and EQ VAS values of the average Hungarian population by age groups

Source: [8] (figure by author)

Comment: The EQ VAS values are presented multiplied by 0.01.

The health statuses of the average populations show differences between the various countries, as also highlighted by EQ-5D population surveys [8]. By comparing Hungary's and Germany's results one can see that although the proportion of people reporting some or extreme problems is the highest in the pain/discomfort dimension and in the self-care dimension the lowest, the differences between the two countries are significant. The proportion of people reporting problems is higher in all the five dimensions in Hungary. It is worth noting that in the anxiety/depression dimension the ratio of people living with problems is nearly 35% in Hungary, while in Germany it does not reach 5%. (Figure 9)

Y: Proportions of people reporting some or extreme problems (%)

X: mobility, self-care, usual activities, pain/discomfort, anxiety/depression

Jelmagyarázat: Hungary; Germany

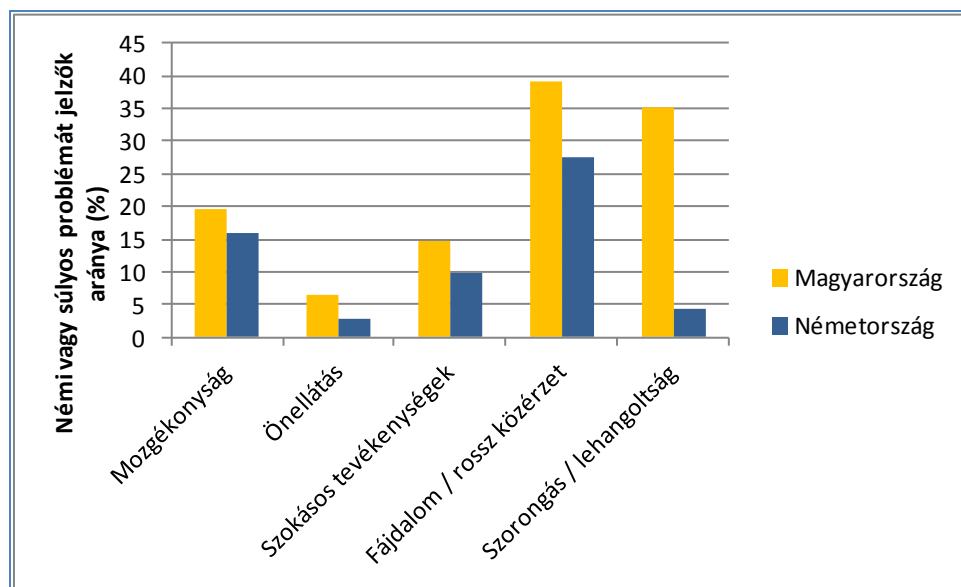


Figure 9 The proportions of people reporting some or extreme problems in the dimensions of the EQ-5D in the average German and Hungarian populations

Source: [8] (figure by author)

The indices calculated from the people reporting problems in the five dimensions of the EQ-5D are nearly the same among the youngest adults, but the difference increases with age; the health status of German citizens is better. (Figure 4)

Y: EQ-5D index, average

X: Age group (year)

Hungary; Germany

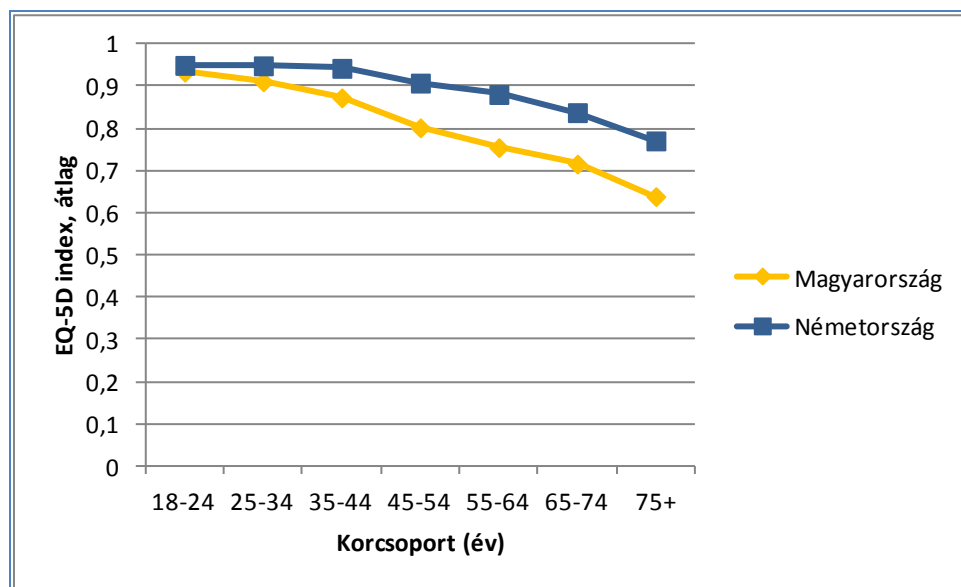


Figure 4 The average of the EQ-5D indices in the average German and Hungarian populations by age groups

Source: [8] (figure by author)

Illness-related decreases in the quality of life can be detected by general quality of life measures. In polyarthritis disease (rheumatoid arthritis, RA) it can be proved by the EQ-5D questionnaire that the disease leads to a considerable decrease in the quality of life. An RA patient aged 20-30 whose illness is active (e.g. with many swollen, painful joints, is easily tired with limited mobility) is in a worse health status than the average Hungarian population aged 70-80. Figure 5 shows the average values by age groups of RA patients whose illnesses were not controllable by synthetic disease modifying medicines (e.g. methotrexat or leflunomid tablets) and started more expensive, newer treatment methods, so-called biological drugs. The survey was conducted right before beginnings biological therapy [9].

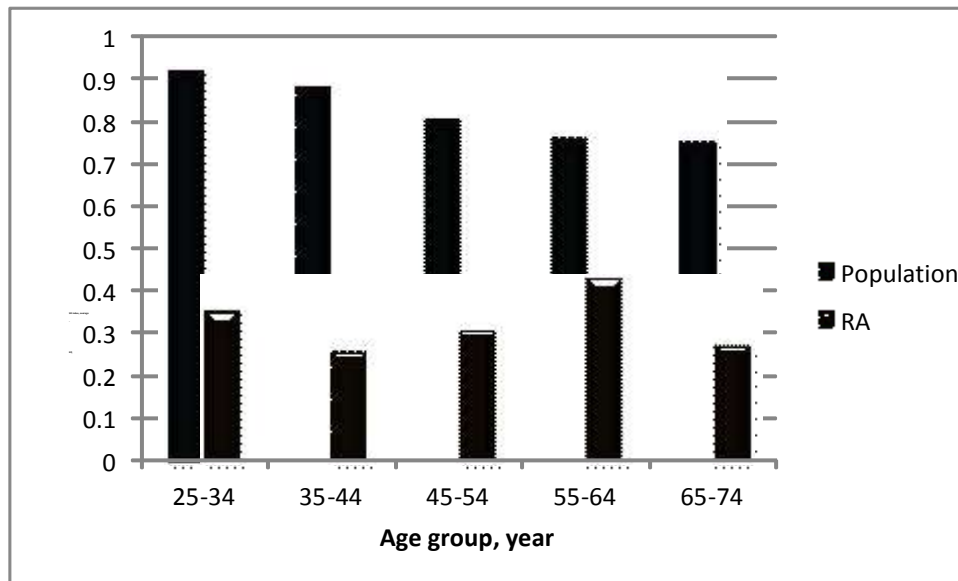


Figure 5 polyarthritis patients (rheumatoid arthritis, RA) with high disease activity compared to the Hungarian EQ-5D population norm

Source: [9,7] (figure by author)

The population norms may differ greatly from country to country (Figure 4). That is why it is important in research to use norms from the same country to demonstrate disease-related decreases in the quality of life.

5.2.2. Disease-specific measures

The quality of life measures presented above cannot often provide sufficient information about the health problems characteristic of particular diseases. Disease-specific questionnaires are specifically designed for a given disease and they focus on the characteristics of the illness to be investigated. They consider the symptoms especially typical for the disease examined in greater detail. Thus, their sensitivity is greater too. Disease-specific questionnaires are very useful for detecting the efficacy of an intervention. Their disadvantage, however, is that clinical significance is easy to obtain; they might enlarge even a slight health benefit. In everyday medical practice they are used for surveying special needs and monitoring patients. They cannot be applied for decisions related to dividing resources among various therapeutic interventions.

Figure 6 shows an excerpt from a disease-specific measure developed for bladder cancer, the Bladder Cancer Index (BCI) questionnaire [10]. (Figure 6) In bladder cancer the bladder may have to be removed completely and the disposal of urine must be solved by, for example, a bag mounted on the abdominal wall. With the development of surgical techniques there is now a possibility for a carefully selected group of patients to receive a new bladder to replace the old one from a bowel segment. Thus, the patient can continue to discharge urine through the urethra. With time most patients learn to control the new bowel-bladder well. A key question in medical decision-making is: what effects a disease and the various therapies have on the quality of life? The BCI examines bladder cancer-related quality of life in three areas: urinating, defecating and sexual life. It surveys, on the one hand, the limitations of these functions and also how much they disturb and cause problems to the patients, on the other hand. (Figure 6)

6. Over the past 4 weeks, which of the following best describes your urinary leakage when you are sleeping?						
No control whatsoever.....	1					
Frequent dribbling.....	2	(Circle one number)				27/
Occasional dribbling.....	3					
Total control.....	4					
7. How big a problem, if any, has each of the following been for you during the past 4 weeks? (Circle one number on each line)						
	<u>No Problem</u>	<u>Very Small Problem</u>	<u>Small Problem</u>	<u>Moderate Problem</u>	<u>Big Problem</u>	
a. Urine leakage causing skin irritation.....	0	1	2	3	4	28/
b. Urine leakage causing body odor.....	0	1	2	3	4	29/
c. Blood in the urine	0	1	2	3	4	30/
d. Pain related to urination, stoma or catheterization.....	0	1	2	3	4	31/
8. How big of a bother, if any, has your bladder, stoma, neo-bladder or catheterizable pouch been for you during the past 4 weeks?						
No bother.....	1					
Very small bother.....	2					
Small bother.....	3	(Circle one number)				32/
Moderate bother.....	4					
Big bother.....	5					
9. Over the past 4 weeks, how much have difficulties with your bladder, stoma, neo-bladder or catheterizable pouch limited your activities? (Circle one number on each line)						
		<u>Not at all</u>	<u>A little bit</u>	<u>Some what</u>	<u>Quite a bit</u>	<u>Very much</u>
a. Social activities with friends.....	0	1	2	3	4	33/
b. Exercise	0	1	2	3	4	34/
c. Sleep	0	1	2	3	4	35/

Figure 6 Bladder Cancer Index (BCI): Disease-specific quality of life measure for people with malignant bladder tumour disease (excerpt) [10]

5.2.3. Assessing the suitability of quality of life measures

Because of the growing number of quality of life questionnaires it is an ever-increasing challenge to decide which questionnaire or questionnaires to use in a given study. In the assessment of questionnaires the following characteristics need considering [11].

- Validity of content: Do the items of the questionnaire examine what we want to measure, was it designed for our target population, is it suitable for measuring that, does the design suit

our goals, are the items comprehensible, can the target group really understand and fill out the questionnaire?

- Inner consistency: How much do the items, sub-scales of the questionnaire correlate, how homogenous are they? (e.g.: if we want to measure a particular thing by several items)
- Validity of criteria: How do the values of the questionnaire relate to the measures regarded as the gold standard of the given area?
- Edited validity: What is the relationship between the questionnaire and other measures? Does it suit the previously defined hypotheses, which are specified as much as possible?
- Reproducibility: How similar are the results produced by two measurements in the case of repeated measurements of an unchanged population?
- Responsivity: Is it suitable for measuring clinically significant changes?
- Floor and ceiling effects: This phenomenon occurs when a specified proportion of the respondents (usually 15-20%) reach either the lowest or the highest values of the questionnaire.

The detailed presentation of these psychometric characteristics and statistical trials is beyond the scope of this volume. For those who wish to explore the topic in depth there is great literature available both in Hungarian and English [11,12].

5.3. MEASURING UTILITY FOR HEALTH STATUS ASSESSMENT

The same health status may have different values for different people. Depending on their values, previous experiences and expectations related to life and health, people attach different values to a given status. Similarly, the same person may regard one of two health statuses as more desirable while the other regards it as less attractive. In other words, he/she may prefer one to the other, or assign greater utility to it.

In a health economic sense utility is the measure of preference for a specific health status or outcome. As a consensual basis, the utility of perfect health is taken to be 1 and death is 0. Health statuses between these two extremes are assigned specific utility values [13,14].

5.3.1. Direct utility measurement methods

Three kinds of utility measurement methods are presented briefly below. Two of these methods measure how much a given status is preferred by someone, i.e. how great its utility is, by how much of his/her life he/she is willing to sacrifice for it. In the third method a given health status or statuses are to be placed along the perfect health - worst health status scale to express their relationship between one another or the extreme points of the scale.

In *time trade-off* (TTO) it is evaluated on the basis of a given health status how many years of the rest of his/her life an individual would give up to regain perfect health. The theoretical consideration in the background of the tool is that people in a bad health status give up more remaining life years than those in a better one. If someone would give up 4 of his/her 40 remaining life years to live a shorter life but in better health, the value of the given status on the 0-1 scale is 0.9 ($1-4/40=0.9$). The consideration is influenced by several factors, e.g. how much the given person believes he/she will live for 40 more years, how far or near future he/she needs to think about (in the case of a young or an elderly person).

During the *standard gamble* (SG) the utility of a given health status is assessed on the basis of undertaking the risk of death. The premise here is that people in a worse health status undertake interventions with a higher risk of death than people in a better one. If for a respondent a 10% risk of death is equal to a given health status, the value of utility is 0.9.

The *visual analogue scale* (VAS) has two defined terminal points and the respondent marks the value of his/her health status on it to be compared with other statuses.

Preferences for a given status are also measurable in other ways, e.g. by how much a patient would be willing to pay to regain perfect health, or if he/she would choose status A or B after the cumulative consideration of various aspects. The three direct utility measurement tools introduced above all have their advantages and disadvantages. The same health status usually produces different utility values depending on the method applied. A given status may be rated worse by time trade-off than by standard gamble because in the first one some time of the future life has to be sacrificed, while in the standard gamble the risk of immediate death is weighed. And in the visual analogue scale method no years have to be given up; the same status may easily get a worse rating than by time trade-off.

5.3.2. Indirect utility measurement

Applying the above-mentioned direct utility measurement methods (time trade-off, standard gamble, visual analogue scale) for large samples is difficult, time-consuming and costly. By using indirect methods the utility of a health status can be measured more easily, and it also allows an assessment of the statuses from a social perspective.

The popularity of the EQ-5D questionnaire is partly due to the fact that by its application utility values can be obtained in an indirect way.

By filling out the descriptive part of the EQ-5D well-specified health statuses are defined. In its 3-level response version the answers are numbered as follows:

1= no problems

2 = some problems

3 = extreme problems

The completed questionnaire can be described by a series of numbers, e.g. if a patient has some problems only in the mobility area (some problems walking), the following series of numbers belongs to the given health status:

2 1 1 1 1.

The health statuses thus defined were evaluated by the population, on a large sample, applying direct utility measures. (Figure 7)

EQ-5D, descriptive part, (from patients): 1= no problems 2= some problems 3= extreme problems		Utility of health status (society)
	conversion	
	Evaluation by population (time trade-off)	

Figure 7 The utility values of health statuses identifiable by the EQ-5D-3L questionnaire from the perspective of the population

The utility values associated with the health statuses describable by the EQ-5D make it possible to assess the patient's health status from the patient's point of view and also couple it indirectly with social value, which can be used in health economic analyses, just by filling out this simple questionnaire.

5.4. THE ROLE OF THE QUALITY OF LIFE IN HEALTH ECONOMIC ANALYSES

Economic analyses are characterized by the study of options, and their objective is the comparative analysis of alternatives on the basis of their costs and results, i.e. outcomes. Health economics deals with the alternatives of allocating scarce resources in the areas of health in the widest sense of the word.

The most commonly used health economic analyses are the following: disease cost and disease burden analysis, cost minimization analysis, cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis.

In the latter three the expenses and the health benefits, in the widest sense of the word, are examined for the various alternatives in a comparative way in order to see how the costs and health benefits of the available therapies and the new therapy compare.

Health benefits are measurable and assessable in various ways. The three analyses differ in this respect mainly. Cost-utility analysis plays a key role in health technologies, especially in the subsidization of medicines by the social security. In order to understand how it works a new measure, the so-called "QALY", has to be introduced first.

5.4.1. Quality Adjusted Life Years – QALY

The concept of Quality Adjusted Life Years was created for the joint expression of life years gained and their quality. The English abbreviation QALY is used in Hungarian scientific articles too.

But what is QALY exactly?

One QALY is equivalent to 1 life year spent in perfect health. The "Q" part (quality) of QALY is determined by utility measurement, where 0 stands for death and 1 for a perfect health status.

A hypothetical example:

Somebody is walking in the street, then suddenly collapses and dies. Passers-by start resuscitating him, meanwhile the ambulance arrives too and he is successfully reanimated. The man lives for another 10 years, then dies. What is the health benefit of the resuscitation? If only the duration of life is regarded, 10 more years were gained by the reanimation. So, the health benefit is 10 years.

The question, however, is in what health status or in what health-related quality of life he spent those 10 years gained?

As an illustration, four hypothetical versions follow, where the person of the example above lives for different durations in different qualities of life.

- a.) After the resuscitation he gets up and continues on his way in perfect health, enjoys absolute health, but suddenly dies one year later.
- b.) After the resuscitation he gets up and continues on his way in perfect health, enjoys absolute health, lives another 10 years in perfect health, then suddenly dies.
- c.) For one year after the resuscitation he is not in full health yet, because during the resuscitation he suffered rib fractures; his health-related quality of life on a 0-1 scale is only 0.5. However, he gets better after that and enjoys perfect health for 9 years, then suddenly dies.
- d.) After the resuscitation he is not in full health; because of his heart problems his health-related quality of life on a 0-1 scale is only 0.5 for 8 years. Then his condition deteriorates further, lives 2 more years with a 0.1 quality of life, then dies.

Obviously cases a.) and b.) are not realistic; immediately after resuscitation nobody is expected to live on in perfect health. The examples are only meant to help with the easy understanding of the concept of QALY.

In case a.) the gain by the resuscitation in the duration of life is only 1 life year, while in cases b.), c.) and d.) it is 10 years.

Question: How many quality life years (QALY) the resuscitation provided in cases a.), b.), c.), and d.)?

Answer: a.) 1 QALY
 b.) 10 QALY

c.) 9.5 QALY

d.) 4.2 QALY

See: **Hiba! A hivatkozási forrás nem található.**, Figure 9, **Hiba! A hivatkozási forrás nem található.**, **Hiba! A hivatkozási forrás nem található.**

Y: Quality of life

X: Life years

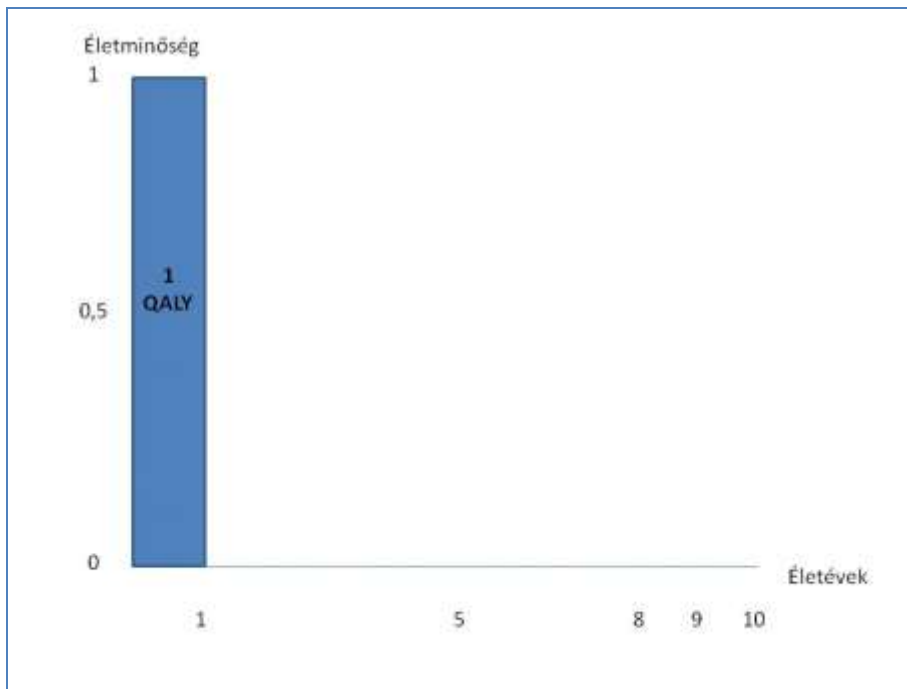


Figure 8 Case a.) from the example: immediately after the resuscitation the person lives on in perfect health for 1 more year, then suddenly dies.

Y: Quality of life

X: Life years

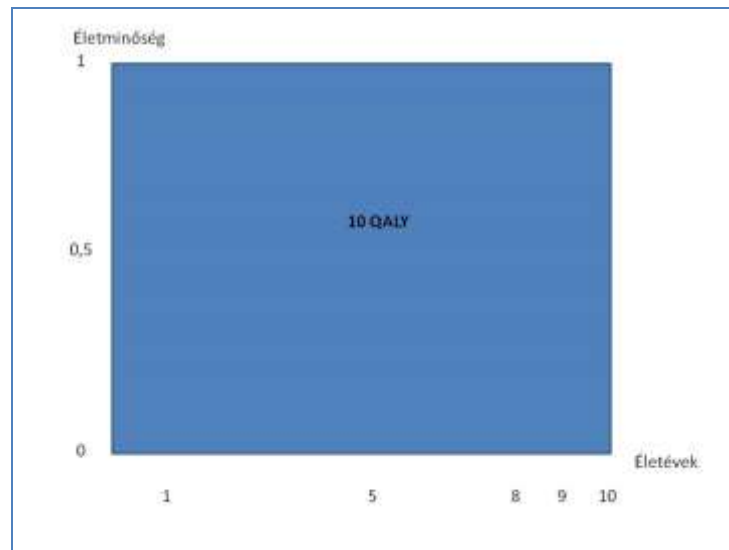


Figure 9 Case b.) from the example: immediately after the resuscitation the person lives on in perfect health for 10 more years, then suddenly dies.

Y: Quality of life

X: Life years

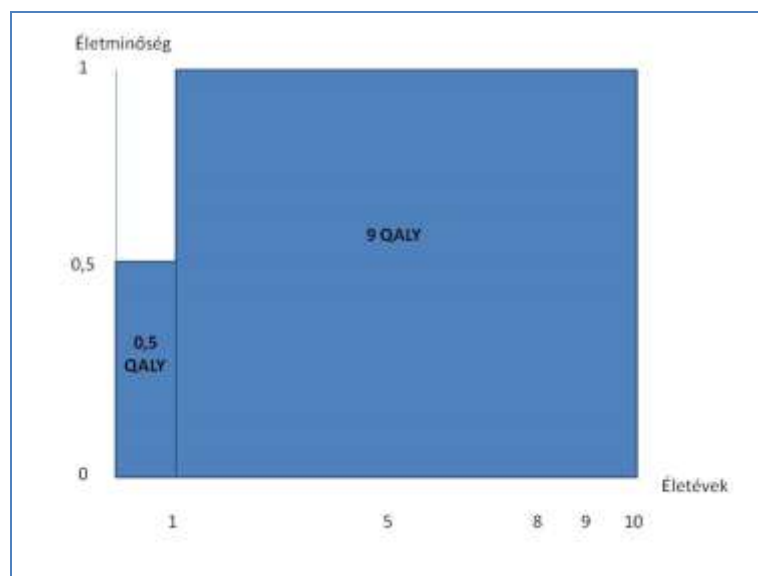


Figure 10. Case c.) from the example: for one year after the resuscitation the person is not in full health yet (value of 0.5 on 0-1 scale), then he recovers fully, lives for 9 more years in perfect health, then dies suddenly.

Y: Quality of life

X: Life years

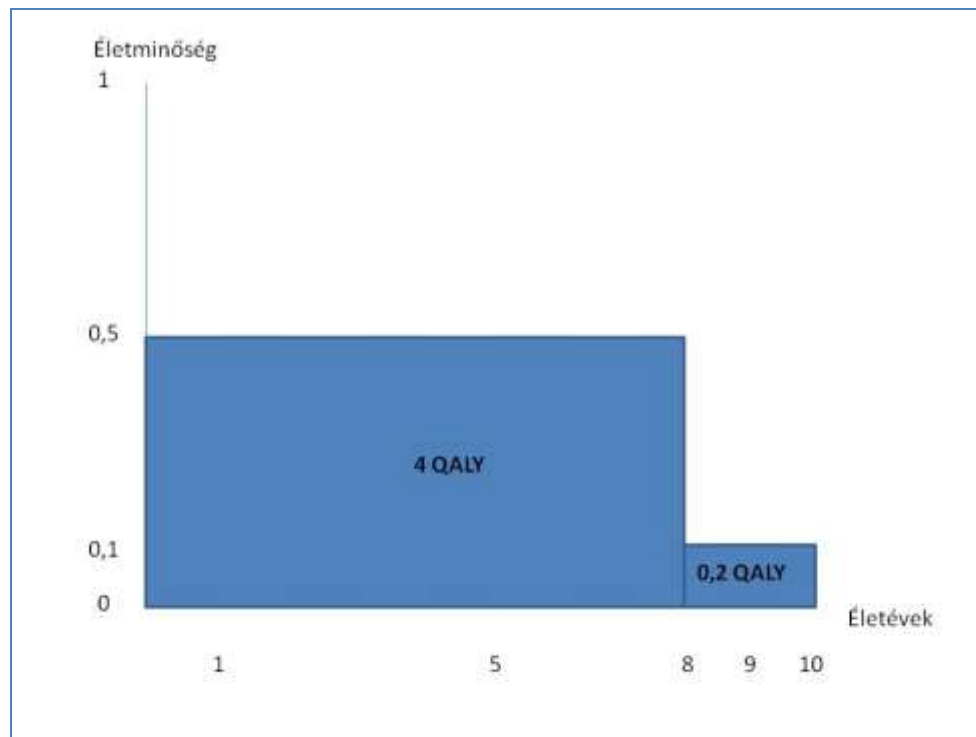


Figure 11 Case d.) from the example: for 8 years after the resuscitation the person is not in full health (value of 0.5 on 0-1 scale), then his health suddenly deteriorates further and lives for 2 more years in very bad quality of life (value of 0.1 on 0-1 scale), then dies suddenly.

Nevertheless interventions in healthcare are not about bringing people back from death most of the time but about recovering the health-related quality of life or decreasing its deterioration.

A simple example of that could be a case where a patient's quality of life is only 0.5 on a 0-1 scale due to his knee problems. If his knee problems are completely eliminated by a successful prosthesis operation and a complete health status is reached, and then he lives on for 10 more years, then he suddenly dies, a 5-QALY gain was achieved by the knee operation.

(Hiba! A hivatkozási forrás nem található.)

Y: Quality of life

X: Life years

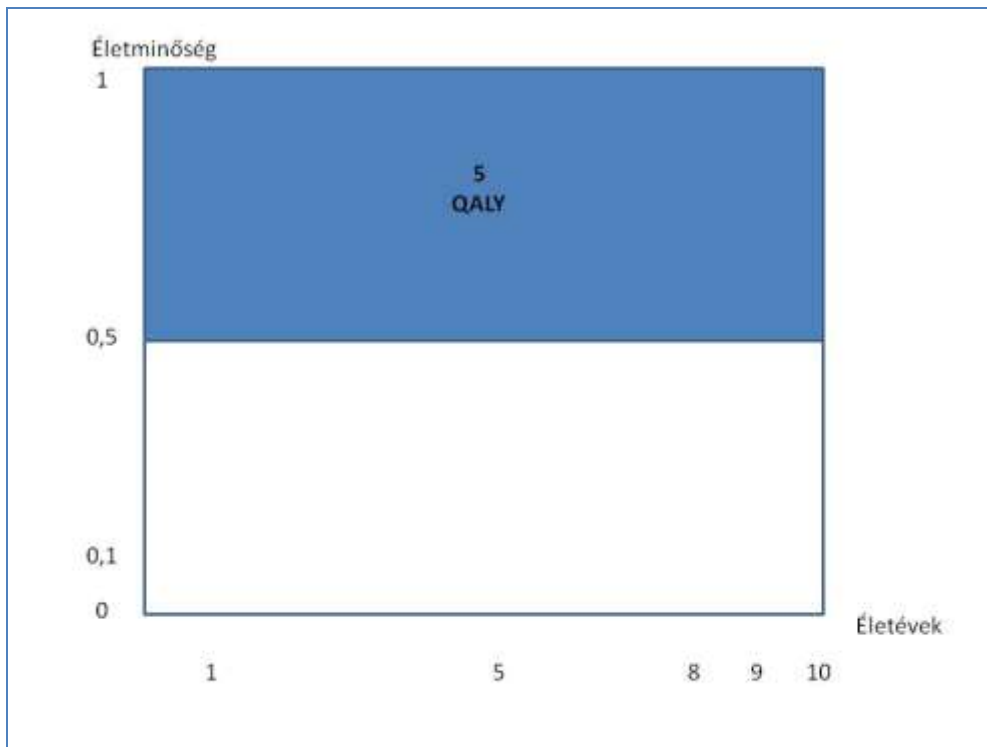


Figure 12 Example: by the knee prosthesis operation the patient's quality of life improved to 1 from 0.5, then lived on for 10 years, then died suddenly.

In chronic diseases, where the clinical picture causes a gradual deterioration of the quality of life, a health benefit can be gained by slowing down the progression. By considering the life years and the quality of life together one can calculate the number of QALY obtainable. **(Hiba! A hivatkozási forrás nem található.)**

Y: Quality of life

X: Life years

	Progression of disease with treatment
Health benefit	
	Natural progression of disease

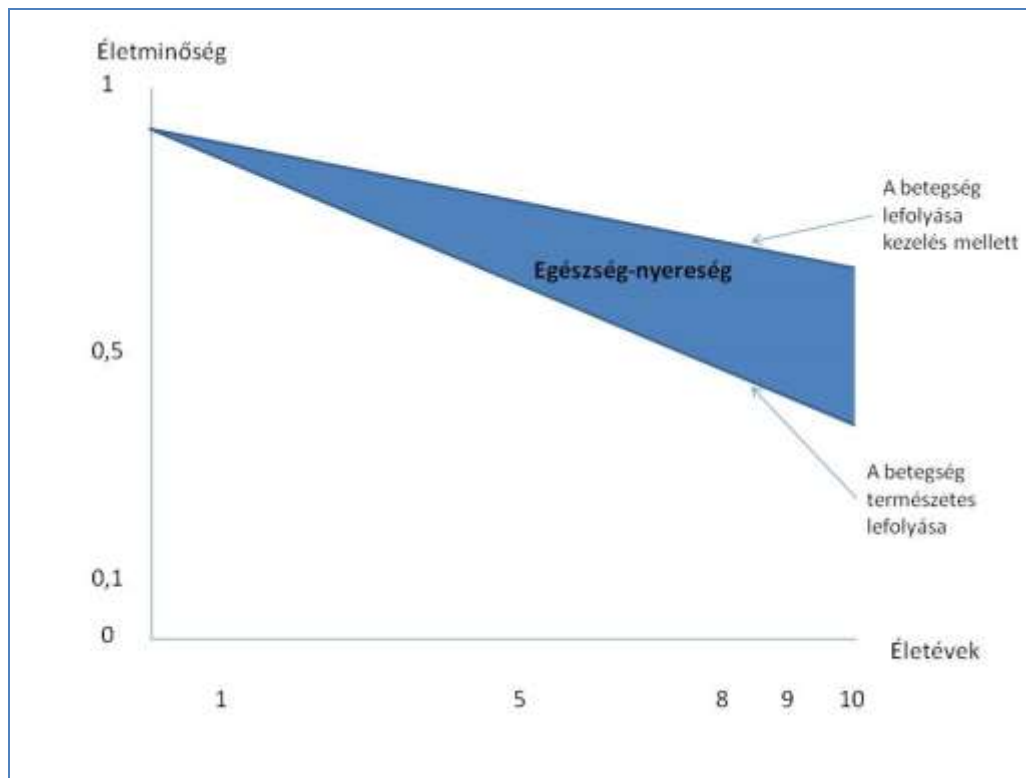


Figure 13 Health benefit obtained by the treatment of chronic disease causing a deterioration of quality of life

Of course, there is never an analogous scale of the changes of a patient's quality of life, similarly to his/her body temperature or fever. In reality, quality of life values are taken by repeated measurements (e.g. annually) during monitoring the patient, and for the time periods between measurements estimates are applied, e.g. between two measurements the patient's quality of life was constant or decreased linearly. It may well happen that there are no measurement values available for the period preceding death, but it is known that the patient was in a bad condition for a longer period (weeks or months). In such a case estimates can be made also for that period for calculating QALY gain. **(Hiba! A hivatkozási forrás nem található.)**

Y: Quality of life

X: Life years

	Progression of disease with treatment
Health benefit	
	Natural progression of disease

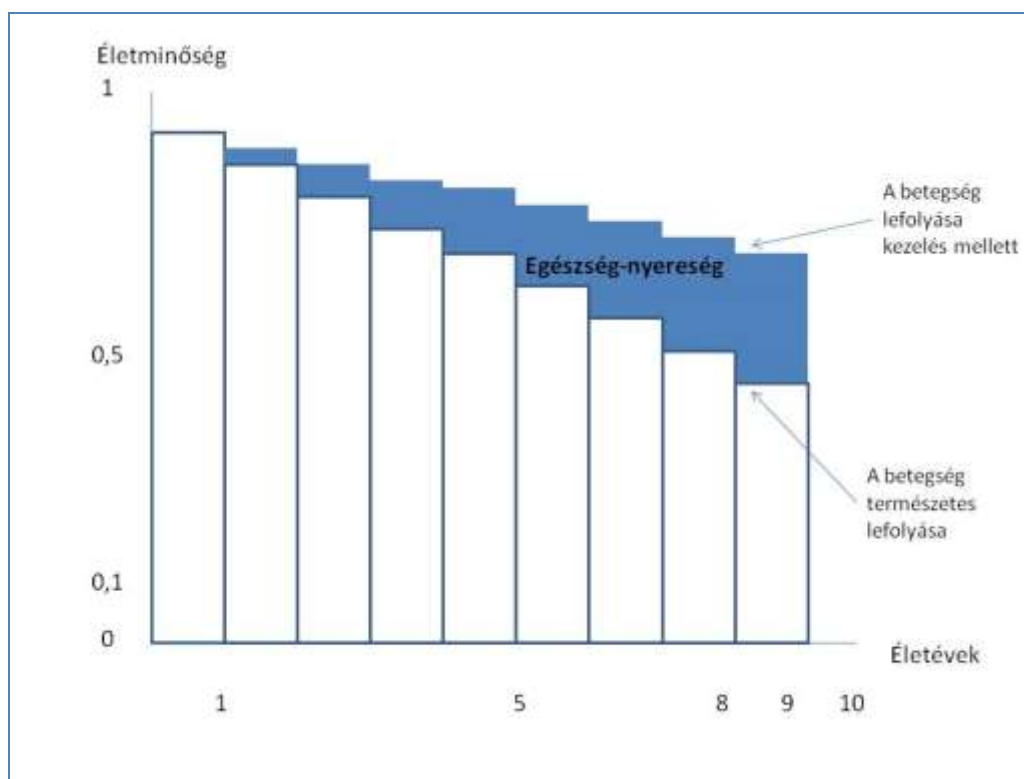


Figure 14 Measuring health benefit by yearly quality of life measurements: assuming that the patient's condition stagnates between two measurements.

5.4.2. Cost-effectiveness and cost-utility analyses

Cost-effectiveness analyses are usually suitable for comparing different procedures within one medical indication because they compare costs and outcomes typical for diseases. The analysis provides information on the additional costs required for achieving a unit of health benefit (incremental cost-effectiveness ratio, ICER). (It should be noted that the comparison does not necessarily produce additional expenses on the costs side, savings may also occur). The health benefit may be a change of a disease-specific quality of life outcome, but it may also be, e.g. the number of swollen joints or prevented heart attacks. Although cost-

effectiveness analyses are very informative within a given disease, they are not suitable for comparing different illnesses.

Cost-utility analyses compare costs also to health benefits. However, regarding the latter they also take changes in life duration and the quality of life into consideration. This ratio is expressed by the incremental cost-utility ratio (ICUR). The denominator of the cost-utility analysis is the QALY, by which it becomes possible to investigate by what additional costs a unit of health benefit (namely 1 quality life year, or Quality Adjusted Life Year) is obtainable by different therapies. In the literature ICER and ICUR are often used (incorrectly) as synonyms; it is the examination of the outcome that helps decide whether a cost-effectiveness or a cost-utility analysis was actually carried out. In many countries the subsidization of drugs by the social security is subject to a health economic assessment: the distributor of a drug has to provide information also on the cost-utility of the drug in the given country. That is why more and more cost/QALY analyses are found in the literature and quality of life measurements are becoming more and more important, especially health status utility measurements [16].

Abbreviations

SF-36	Short-Forf 36 (health status questionnaire)
EQ-5D	health status questionnaire
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
ICUR	incremental cost-utility ratio
KSH	Hungarian Central Statistical Office (Központi Statisztikai Hivatal)
QALY	Quality Adjusted Life Year
SG	standard gamble
TTO	time-trade-off
VAS	visual analogue scale

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6. PATIENT SATISFACTION SURVEYS (D. ENDREI, I. TRAIBER-HART)

6.1. ABOUT PATIENT SATISFACTION SURVEYS IN GENERAL

The point of satisfaction measurements is that managements get a realistic, precise picture of a product or service being examined. Successful satisfaction measurements require well-defined goals, scopes and an extensive methodology. The involvement of managers and staff is in the process also indispensable.

The main steps of a satisfaction survey are the following:

- The definition of the area/topic to be measured.
- The selection of the target group of the satisfaction survey.
- The preparation of the questionnaire after consulting the managers of the areas involved.
- The evaluation and analysis of the results obtained.
- The preparation of a written summary that also contains suggestions for the problem areas.
- Feedback and presentation for the management.

The methodological tools of such surveys:

- The interview, the purpose of which is to provide stakeholders with as much relevant information as possible.
- The traditional self-administered method, in which the questionnaire contains statements, remarks and opinions that the respondent has to consider and decide to what extent he/she believes them to be true or agrees with them.
- The online questionnaire that most multinational companies operate these days with the help of data collection systems and use software for filling in and processing questionnaires on their servers.
- Telemarketing activities through mediators.
- The personal cooperation of interviewers.

The most common areas of satisfaction surveys:

1. *External surveys* can be done among the clients or consumers, suppliers and other partner providers.

Their goal is to survey the characteristics of a product or service or the situation of corporate policy or the market conditions.

2. *Internal surveys* are carried out among the personnel and organisations/departments within a company.

They focus on finding out about opinions related to the operation, exploring and prioritizing internal problems and formulating development plans.

Quality assurance philosophy in healthcare services

Total Quality Management (TQM), a quality management philosophy widely accepted among Hungarian healthcare providers, also prescribes learning about ever-changing customer needs. The basis of the International Quality Award is compliance with further requirements by organizations that already excel in total quality management. It is necessary for them to meet all the criteria of the excellence model of the European Foundation for Quality Management (EFQM), where the fulfilment of the requirements is evaluated by scores. Five so-called “enablers” and four “results” are examined.

The five “enablers” are the following:

- 1) Leadership
- 2) Strategy
- 3) People
- 4) Partnerships and resources
- 5) Processes, products and services

The four “results” as reflected by performance are the following:

- 1) Customer results
- 2) People results
- 3) Society results
- 4) Business results

In 1996 Hungary also launched its National Quality Award programme, which has been announced by the Ministry for National Economy every year ever since. The Hungarian National Quality Award follows the European model. In the beginning only industrial organizations and service providers could compete for it but since 2006 public service organisation have been allowed to enter too.

The Hungarian requirements are the same as the European. Consequently, Hungarian award-winning organisations have developed their excellence models according to the same principle, where consumer satisfaction results is the criterion that can be awarded the highest

score of all the 9 requirements. The Hungarian award-winners achieved their greatest successes in Europe between 2000 and 2009. According to the 2009 survey Hungary came 5th among the most successful countries in Europe after Spain, the UK, Germany and Turkey.

Table 1: Winners of the National Quality Award 1996-2009 (excerpt)

Year	Healthcare provider
2007	András Jósa Hospital of Szabolcs-Szatmár-Bereg County, Nyíregyháza
2006	Zala County Hospital, Zalaegerszeg
2000	MEDICOR Hand Instrument Co.

Source: Partnership for Excellence, Hungarian partner of EFQM

6.2. STANDARD INTERNATIONAL METHODS IN PATIENT SATISFACTION

MEASUREMENT

Western healthcare providers have monitored public opinions and the processes and effectiveness of health treatments since the beginning of the 1990s. The Norwegian Knowledge Centre for the Health Services published a report about a national and international survey on patient satisfaction in 2008. [6] The project analysed the methodology and results of satisfaction surveys carried out in the 10-year period from 1997 to 2007. According to the research results published in 2008 Denmark, the United Kingdom, Holland, Norway and the USA had already had national programmes for surveying patient satisfaction (for certain areas of hospital care) earlier. The goals of the national surveys reflected social needs. One point in common, however, was noticeable everywhere: the surveys could provide data related to their own activities. It is well-known that a society's healthcare expenditure is influenced by its values concerning health policy, the economy and science, but as a new aspect of evaluation the harmonization of consumer requirements and the quality of services appeared in the last decade too. In some countries patient satisfaction surveys were carried out as a part of the institutional accreditation process but it was not prescribed or compulsory. For surveying the experiences related to hospital care questionnaires with a varying number of items were used. A summary is shown in Table 2.

Table 2: The number of the question in the questionnaires used in the individual countries

Country	Year of introduction	Number of questions
USA	2008	27
United Kingdom	2010	87
Ireland	2000	142
Norway	1996	53
Denmark	2006	23
France	2001	36
Austria	2010-2011	67
Germany	2011	15

Later organizations providing services realized that they needed short questionnaires to facilitate responding. In 2008, the year of their publication, the Norwegian Knowledge Centre for the Health Services developed a short, 10-item questionnaire, the GS-PEQ (Generic Short Patient Experiences Questionnaire), to find out the opinions of patients in specialized medical care. [15] From the Picker Institute's 100-item questionnaire for inpatients researchers selected the 15-item PPE-15 (Picker Patient Experience Questionnaire), which has been regarded by researchers as a set of basic questions ever since. [9] [14] The researches on consumer satisfaction and the assessment of healthcare providers in the United States, CAHPS (Consumer Assessment of Healthcare Providers and Systems), also serve as reference research material for the surveys of patient satisfaction in several countries. [1]

6.2.1. The United States

In the United States the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys the issues related to patient satisfaction in the framework of its special programme. [1] Participation in the survey is voluntary, except for healthcare providers that participate in national programmes supporting hospitals with financial resources and may only use that support for developing quality services. For them it is compulsory to conduct monthly patient satisfaction surveys, which are carried out by using a 27-item, standardised questionnaire, named: Hospital Survey (HCAHPS). It can be completed by mail or telephone at least 48 hours and maximum 6 weeks following discharge. At a national level the survey is coordinated and processed by Centers for Medicare & Medicaid Services (CMS). The survey

results are corrected by the national average of the variables of the composition of patient populations for each hospital. [4] Since 2008 ten HCAHPS indices have been published for each participating hospital on the website of Hospital Compare, which compares the hospitals. Patients can give scores on a 0-10 scale. The questions are in connection with the topics of informing patients, communication, pain control, the administration of drugs, the cleanliness of premises, the provision of a quiet environment, things to do at home after discharge and lifestyles. The publication of the results urges the hospitals to improve the quality of their services and also creates competition in the healthcare market.

6.2.2. The United Kingdom

In the United Kingdom yearly patient satisfaction surveys have been compulsory in the framework of the national programme that assesses patients' opinions (National Patient Survey Programme) since 2002. The commission that supervises the quality of care, Care Quality Commission, is responsible for the surveys. In 2010 the survey on inpatient care was conducted in 161 trusts. The trusts mailed the questionnaires to 850 randomly selected patients following discharge from hospital. The number of completed questionnaires exceeded 66 000. The 87-item questionnaire used in the survey was prepared by the NHS Surveys coordination centre, operated by the Picker Institute Europe. [14] The Care Quality Commission publishes the results of the survey in a national conspectus as well as broken down by the trusts [3], and it also uses the results for its controlling activities. The Department of Health uses the results for measurements by performance indicators and statistical analyses.

6.2.3. Ireland

In Ireland the Irish Society for Quality and Safety in Healthcare (ISQSH) has been responsible for surveying inpatients since 2000. The results of the survey published so far (of 2010) were attained by processing a large number of samples, considering the opinions of more than 5000 patients. [7] The respondents here were also patients treated by state hospitals. The sample sizes differ by hospitals, considering the size of the institutions and the number of patients treated. Similarly to the USA, here also the method of mailing questionnaires to patients following discharge from hospital was preferred. The questionnaire consisted of 142 questions. In order to ensure a suitable sample number and a successful survey non-responding participants were sent reminders three weeks after mailing the

questionnaire, repeated a month later. The patients could also answer the questions over the telephone using the help line made available for the duration of the survey. The use of multiple choice questions and the answers given to open-ended questions in the questionnaire meant that during the analysis of the data variance analyses were also applied besides basic, descriptive statistics (frequency tables).

6.2.4. Norway and the Nordic countries

The Norwegian Knowledge Centre for Health Services (NOKC/Kunnskapssenteret) [12] has prepared patient satisfaction surveys since its foundation in 2004. Patients' experiences related to hospital care are assessed by applying the Patient Experiences Questionnaire (PEQ). In the 2006 national research 10912 questionnaires were processed. Also here, patients were contacted by mailing them a 53-item questionnaire one-two weeks following their discharge from hospital. A considerable part of the questions was aimed at the experiences of hospital treatments and to a lesser extent at changes experienced in health status, the actual health status and the background factors of patients. Those who did not answer for four weeks received a reminder. The research results were published at national and regional levels, and the comparisons between the hospitals were also made public. In 2008 the NOKC developed a 10-item, short questionnaire to survey satisfaction concerning specialist medical care, the Generic Short Patient Experiences Questionnaire (GS-PEQ). [15]

The organization of the Nordic countries (Norway, Finland, Sweden, Denmark and Iceland), the Nordic Council of Ministers established the Nordic Working Group of Quality Measurement in order to develop quality indicators for comparisons between the Nordic countries.

The NORPEQ questionnaire is the result of the efforts of the working group.

The questionnaire, consisting of only eight items, can be incorporated into the already existing national questionnaires. Experimental surveys with the questionnaire were made in Finland, Sweden and Norway in 2009. [13]

6.2.5. France

Telephone surveys about the patients' satisfaction with hospital care were conducted for French hospitals annually from 2001 till 2010. After a year's pause, from 2012 surveys using the 36-item SAPHORA-MCO questionnaire again became compulsory for hospitals with active beds. [11] The institute appointed to carry out the research required 240 sets of patient

data from each hospital, on the basis of which they had to conduct 120 interviews per institution. The personnel of the surveying institute started phoning patients two weeks after their discharge from hospital. After 12 unsuccessful phone calls they did not try to contact the patient any more. The main goal of the survey was the development of treatment quality. The evaluation was carried out by the Technical Agency of Hospitalization Information (ATIH).

6.3. AUSTRIA

The first national hospital patient satisfaction survey in Austria was conducted in 2010. The goal of the survey was a sector-wide comparison to facilitate the improvement of the entire care process. The survey was managed by the Gesundheit Österreich GmbH/BIQG (Bundesinstitut für Qualität im Gesundheitswesen) commissioned by the Federal Ministry of Health. In the Austrian survey the experiences of the ensured were measured from the moment of arrival at hospital through discharge up to the processes related to aftercare. The BIQG used a 67-item questionnaire especially developed for hospitals. Between November 2010 and March 2011 about 22 thousand patients of 49 hospitals completed the questionnaires mailed to them by the hospitals. The survey results were made available to the hospital controlling authorities and the hospital wards (anonymously), so that they could carry out national benchmarking.

6.3.1. Germany

In Germany the Bertelsmann Foundation deals with patient satisfaction surveys at a national level. The Bertelsmann Foundation and the Swiss Outcome Association developed a 15-item questionnaire designed especially for hospitals. They planned the survey of about 2 million patients' hospital experiences annually. For the survey patients insured by AOK/Barmer GEK and discharged at least two weeks and at most eight weeks earlier were selected. In order to improve the response ratio survey participants received two reminders.

In Germany other insurance companies conduct surveys too. The Techniker Krankenkasse (TK), with 5.7 million ensured, started its patient satisfaction surveys in its contracted hospitals in 2006. In the 2010 survey the hospitals where at least 150 patients insured by the TK were treated at the time of the survey took part. Depending on the number of patients treated and the number of hospital beds, 150-1000 insureds from each participating hospital were asked by mail using a 41-item questionnaire. The responses on a Likert scale had a maximum value of 12 points in the case of perfect satisfaction. With more than 200 thousand

questionnaires returned, representative results were achieved in 996 hospitals. [18] The objective of TK with the survey was to make it easier for patients to find hospitals and to identify areas needing development.

6.4. PATIENT SATISFACTION SURVEYS IN HUNGARY

6.4.1. The definition of patient satisfaction

Patient satisfaction is the patients' opinion of healthcare. It is an important factor in the quality of care, and it is primarily influenced by the positive and negative experience gained during care. Consequently, it is a subjective category and is not directly related to changes in health status. On the other hand, it does depend on the patients' status in society, education, values, etc. [5] It can be briefly defined as the measure of satisfying a patient's expectations.

6.4.2. About patient satisfaction in general

Measuring patient satisfaction is an important constituent in the assessment of the quality services of healthcare providers. Interpreting quality in the context of healthcare is complicated as it must represent the degree of the realization of expected needs in preserving, restoring and maintaining health from the participants perspective. Healthcare services typically involve more than two factors. Thus, the opinions of all those involved are important from the aspect of the organization of the services. It also follows that the results of healthcare can be examined from several angles concerning satisfaction, but the most important opinions are those of the patients. However, patients' opinions should also be divided considering the assessment of changes in a patient's condition (recovery outcome) and satisfaction related to the provision of the service. At the same time, this social responsibility is coupled with a shortage of funding, where survival depends on improving the provision of services and the optimization of costs.

Surveys are almost compulsory to do as preparation for basic economic, organization developmental and marketing decisions. For healthcare providers patient satisfaction surveys are a quality development tool, whose purpose is the continuous improvement of the quality of care and the identification of new market demands. The correction of problems detected during the assessment of satisfaction measurements serves the interests of healthcare providers primarily.

6.4.3. An overview of Hungarian patient satisfaction surveys

Major Hungarian institutions providing healthcare services already made efforts to elicit opinions from people receiving care as early as 1993. One of them was the National Institute of Medical Rehabilitation where in 1993 the work of the institute was continuously monitored from the patients' perspective using the questionnaire method. With some research support, the institute sent self-administered questionnaires to 1000 randomly chosen patients who had returned to their homes at least one year earlier. A comprehensive analysis was published about the data collection and the results of the survey. [19]

The First National Patient Satisfaction Survey in Hungary was conducted in 1999 commissioned by the OEP. The company commissioned for the job was Szonda Ipsos (currently Ipsos Media, Advertisement, Market and Opinion Research Institute), which carried out surveys at healthcare providers volunteering as they were interested in their patients' opinions.

In 2001, also upon commission by the OEP, the Social Research Institute (hereafter: TÁRKI) carried out the same survey, with the only difference being that they worked with a larger sample and involved more hospitals. While in the first case the patients were asked directly before discharge, in the latter survey the patients treated and their close family members could fill in the 54- or 37-item questionnaires in their homes. In April 2011 TÁRKI published a two-volume study from the results of the survey. [8]

In 2004 another research took place among patients discharged from hospital. The questionnaire contained 29 questions.

In 2005 there was a national outpatient satisfaction survey.

In April 2009 the National Institute of Primary Care (OALI) published a call for tender for the self-audition of primary care - adult, children's and mixed - practices. Sixty practices participated (30 adult and 15-15 mixed and children's, respectively) and 50 of them carried out the self-audit and submitted the results. At the same time, as part of the programme 2190 patient satisfaction questionnaires filled in by the patients/parents were also submitted.

At present, hospitals also conduct patient satisfaction surveys, however, without a unified methodology. A universally applicable, unified patient satisfaction questionnaire could greatly help healthcare providers. It could ensure comparability between similar institutions.

6.4.4. Expectations about patient satisfaction surveys

The results of satisfaction surveys are only useful if they expose the differences between patients' expectations and the services provided, also considering the given healthcare provider's progressivity level, obligation to provide regional care, the health status and the demographic indicators of the population, etc.

Patient satisfaction surveys repeated at least annually allow the analyses of trends, and can facilitate not only the achievement of satisfaction but also its maintenance. Also, in the case of similar services of healthcare providers operating at the same level of progressivity they can be used for benchmarking.

6.4.5. The steps of conducting patient satisfaction surveys

Identifying the problem, the goal.

1. Making the the generally identified problems measurable, i.e. the formulation of the concrete questions. (In order to facilitate computerized analyses, questions should have simple wording and allow precise record taking, which is most easily achievable by closed-ended question.)
2. Correct sample selection. It is common to use probability sampling, the key concept of which is representativeness, and the main key is random selection.
3. Administering the questionnaires. The most common method is self-administered anonymous, but there are also questionnaires sent by mail or questionnaires administered by a mediator (interviewer).
4. The evaluation and analysis of the survey sample. During the first assessment on the basis of the completion, it can be decided whether a questionnaire is suitable to be included in the survey or not. During the analysis data are processed by various statistical methods.
5. Preparing graphical and written analyses. Graphical presentation is the simplest way of analysing available data. Visual impressions are easier to process than “dry” figures, moreover, they are spectacular and informative. The most commonly used types of charts are the following: 1) bar chart 2) histogram 3) point chart 4) line chart 5) pie chart
6. Feedback in the form of a report for the management.
7. Elaborating the details of actions related to the differences exposed, preparing an action plan.

6.4.6. Aspects of questionnaire construction

The quality of the questionnaires affects the collection of information and the results. The precise construction and testing of the questionnaires is a prerequisite for success.

The main aspects of selecting the right *question types* are: (1) the subject of the survey, (2) the characteristics of the respondents, (3) the planned methods of data processing and analysis. It also matters greatly whether the questions are aimed at facts or opinions.

In the case of using **closed-ended questions** respondents can choose from simple answers. The uniform way of giving answers to closed-ended questions allows simple and quick data processing. It is, however, a disadvantage that fixed questions can never give a complete picture as they may differ from reality and, consequently, distort it.

The advantage of using **open-ended questions** is that unforeseen information can be obtained too. The quality of a respondent's writing (appearance, spelling, wording, etc.) may also provide further background information. Nevertheless, it is a great disadvantage that the processing of many varied answers is time-consuming and their analysis is very difficult.

Besides fixed options **semi-closed-ended questions** also offer the "other" category, where opinions different from the responses provided can also be given.

By using **assessment scales** the presence or absence of something can be found out in a person. However, in the preparation of scales there is a danger of oversimplification and using incorrect measures (categories and distances).

6.4.7. The appearance and structure of a questionnaire

A questionnaire must be **well-organized**, and sufficiently **structured** and **clear**, in other words, it must be conducive to simple and quick completion. Neither too wordy, nor extremely concise questionnaires are acceptable. There must be ample space for responses. For easy tracking, all questionnaires must be numbered, which makes the processing of the returned answers easier.

The stages of creating a questionnaire are: preparation, construction, testing and finalizing. In the preparatory stage the depth of the questions is also determined in accordance with the goal of the survey. **Testing the first version of a questionnaire on a small sample** may also solidify the order of well-designed questions. If possible, the easier, factual questions should come first (e.g. age, gender, education). The order of the rest may be guided by chronology, topics or other (even psychological) considerations. It is in the stage of finalization that the respondents receive the questionnaires.

6.4.8. Instructions and explanatory remarks in questionnaires

Questionnaires must have clear instructions and explanations, where necessary. Even if it may seem superfluous in some cases, it must be clearly communicated to the respondents what is expected of them.

A **short introductory passage** can contextualize the questionnaire and may help respondents prepare for answering. For receiving the right kind of answers, there may be a need to provide further information and clear separate instructions for the particular questions in some question types. In the case of questionnaires with several sections it is worth providing separate explanations for each section.

During questionnaire writing attention should be paid to **the correct use of language** and an appropriate **tone**.

The questionnaire presented below is a sample questionnaire investigating the operation of a ward providing active inpatient care. (Annex 1)

6.4.9. The steps of processing questionnaires

1. The inspection of the questionnaires

For conducting a survey a certain interval is appointed in advance. The conclusion of receiving returned questionnaires is important.

The *formal inspection* of the questionnaires means making sure that the material received can be used according to the criteria below:

- Are the answers legible?
- Are there any missing answers?

The questionnaires found suitable must be inspected for their contents too. The *inspection of the contents* primarily means eliminating any wrong answers and wrong practices of progression within the questionnaire.

If the number and structure of the questionnaires fulfils the set sample number requirements, the actual processing can begin.

2. The coding of the questionnaires and the recording of the data

By coding, the answers in the questionnaire can be identified. This is usually done by simple numbering and the processing also takes place by following those numbers. Processing is assisted by computer software designed for that purpose; manual processing is only used in the case of very small samples. The use of spreadsheets is recommended. The reason for this is that the use of such software generally does not require any special training (office software

are also known by those who do not normally process questionnaires). On the other hand, certain simple calculations can also be carried out by spreadsheets.

A frequency table is created for the recorded data, i.e. it is listed for each question how many times a code occurs in the data set. By comparing the list and the questions of the questionnaire it is established if the recorded codes represent probable data. In the case of incorrect data the questionnaire can be traced back by the number and the data can be corrected.

3. The modes of processing the information

The primary processing of the data may be done by using a spreadsheet. By primary processing the determination of the following characteristics for each question is meant:

- frequency, relative frequency,
- median, mode
- minimum, maximum, range,
- average, standard deviation.

The frequency tables and the statistical parameters serve the assessment of the particular questions; these are the so-called *univariate analyses*. For preparing frequency tables the use of Excel pivot is sufficient too.

For complex, *multivariate analysis* it is advisable to use statistical software designed for that purpose.

Junction tables, relationship analyses

With the help of junction tables the inner systems of relationships of the responses of a questionnaire can be investigated. Regarding the sample questionnaire above, for example, the answers reveal whether the intimacy on the part of the personnel was ensured among men and women or not. Breaking down the responses further, it can also be categorized into which age group of the women what answers were given.

6.4.10. Factors influencing the results of satisfaction surveys

During receiving care patients' judgments are greatly influenced by proper communication and the provision of sufficient information for patients. That is why if a patient does not receive socio-culturally appropriate information suited to his/her level of education, he/she may form a negative opinion due to the unanswered questions. If the expectations of a patient are not matched by the level of services during healthcare, that may lead to further dissatisfaction.

By periodically repeating a satisfaction survey it is possible to avoid the typical mistake where only patients of one age group or those suffering from just one group of diseases are involved in the research. It must also be considered whether a satisfaction survey should only include inpatients during the period of receiving care or discharged patients should also be able to respond from their homes. In the first case it cannot be ruled out that negative events receive too much emphasis, while in the latter patients have enough time to think about their answers. Even if the requirements of constructing patient satisfaction questionnaires are all met, the helpful cooperation of healthcare staff or the assistance of an interviewer may still be needed. However, patients' responses must not be affected by a situation in which they feel they are at the mercy of the staff.

A patient's answers are significantly influenced by his/her individual characteristics, such as sex, age (in the case of elderly people, whether they live alone or in a community), education, position at work (social activities), financial situation, geographical location of his/her home and the mode of accessing the hospital.

From the perspective of the success of a survey it cannot be neglected either whether the person filling in the questionnaire has directly experienced the events of his/her care (examinations, interventions, treatments), or responds only indirectly as a family member, legal representative or guardian. Patients are forced to make false judgements if the questionnaire also contains questions related to the assessment of the professional work, as - with a very few exceptions- patients are not able to judge the performance of medical or nursing work according to protocol.

While conducting a satisfaction survey the time required for the processing and the evaluation as well as the relevance of the measures taken in response to the results obtained (opinions valid at the given time) must also be considered.

6.4.11. Sample patient satisfaction questionnaire

..... Clinic	Patient satisfaction questionnaire for inpatients
..... Ward	

Dear Sir/Madam,

In order to improve the level of care at our clinic we always ask our leaving patients about the experiences they have gathered during the time they spent here. The main goal of our survey is to get to know our patients' opinions of the operation of our clinic. We would like you to share your remarks and opinions with us. Participation is voluntary and anonymous.

Please, circle the answer or **answers that best express your opinion**. At the bottom of the page you can also add your own comments.

1. **Are you filling out this questionnaire as**
 - a patient
 - a close relative
 - a legal representative?
2. **Your sex?**
 - Male
 - Female
3. **Your age?**
4. **What is your current occupation?**
 - Pupil/student
 - I work.
 - Retired (disability retirement)
 - Unemployed
5. **Where do you live?**
 - Town/city
 - Village
6. **Why did you choose this clinic?** (You may also give more than one answer.)
 - I belong here regionally.
 - Because of a certain doctor.
 - Because of good previous experiences.
 - An acquaintance, relative of mine works here.
 - Because of the good reputation of the institution.
 - Because of other reasons:
7. **Had you ever been an inpatient at this clinic in the past?**
 - Yes
 - No
8. **How did you get to the clinic?**
 - Emergency
 - Arranged appointment
9. **After how much time did you receive care?**
 - immediately
 - within 1 hour
 - after 1 hour

10. How many beds were in your hospital room?

- I was alone.
- I was with 2-4 other people.
- I was with 5-6 other people.
- I was with more than 6 other people.

11. Did you get food (special diet) suited to your condition?

- Yes
- No
- Partly

12. What did you think of the mealtimes?

- Appropriate
- Inappropriate

13. How satisfactory was the doctors' work? (5 means complete satisfaction, 1 means that you are not satisfied at all.)

- 1
- 2
- 3
- 4
- 5

14. Did your doctor ensure sufficient privacy during your examination and your meetings after that?

- Yes
- No

15. Could you discuss your questions about your illness with your doctor?

- Yes
- No
- Only partly

16. How was the nurses' work?

- I am completely satisfied.
- I am only partly satisfied.
- I am not satisfied.

17. Did the nurses spend enough time with you?

- Yes
- No
- I cannot judge that.

18. Who helped you with washing, eating, moving?

- Nurse
- Other patient, family member
- Nobody, although it would have been necessary.
- I did not need help.

19. How soon did the nurse reach you if called?

- Immediately
- Within an acceptable amount of time.
- It was very changeable.
- He/she did not come, I had to call again.

20. The administration of your personalized daily medication

- always happened at the same time.
- happened at different times.
- Some times were missed.

21. Considering all your experiences, would you recommend this clinic to others?

Yes

No

22. Other comments, suggestions:

.....

**After completion, please, put the questionnaire in the box marked “Patients’ opinions”
upon leaving.**

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7. THE ROLE OF SCIENTIFIC EVIDENCE (I. BONCZ, R. VAJDA, T. CSÁKVÁRI, D. ENDREI)

7.1. CONCEPTUAL OVERVIEW, DEFINITIONS IN EVIDENCE-BASED MEDICINE

Evidence-based medicine has excellent international and Hungarian literature. Moreover, the Professional Guidelines of the Ministry for the development of evidence-based professional guidelines have been available in Hungary for a long time now.

In this chapter a kind of health economic and health-political methodological approach of evidence-based medicine is presented, pointing out the basic issues and the methodological problems related to it and the possibilities of its everyday application.

For millennia decisions have been made about the care of concrete patients in medical-health scientific practice based on the considered, confident and successful use of state-of-the-art evidence.

It means the conscientious, explicit and cautious application of the best evidence known in making decisions concerning the care of individual patients. A good doctor uses both his/her own clinical experience and the best external evidence available; alone neither is sufficient.

Thus, evidence-based medicine (EBM) is "an approach to clinical decision making about individual patients in which the doctor uses the most reliable, systematically elaborated scientific evidence available and his/her individual clinical experience, in consultation with the patient, to decide upon the option which suits the given patient best.". EBM is normally the competence of healthcare professionals (doctors, chemists, nurses, physiotherapists, dieticians, health visitors, etc.) due to clinical decision-making involved in the care of individual patients.

Evidence-based public health and health policy is the planning, implementation and assessment of effective public health programmes and policies based on the systematic application of scientific data and information also taking the models of behavioural science and programme design into account. In other words, it is the the conscious, considered use of currently existing evidence in decision-making for the protection of a community or population, the maintenance and improvement of its health status and the prevention of diseases. In this respect evidence-based public health and health policy is an approach to decision-making about the population that combines EBM and the results of evidence-based

decision-making. At the same time, however, that means different levels of competence: political, governmental, ministerial and that of the management of the OEP.

All in all, talking of scientific evidence, personal clinical experience must also receive attention just like the values and expectations of the patients, besides external evidence. These three approaches form the so-called EBM triad, i.e. the 3-pole approach, in which scientific, clinical and patients' preferences also prevail.

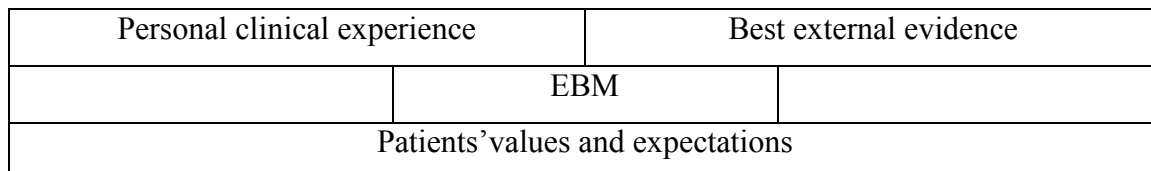


Figure 1

7.2. EFFICACY, EFFICIENCY, EFFECTIVENESS

One of the basic issues of evidence-based medicine is the clarification of concepts used for assessing the efficacy and effectiveness of the individual health technologies..

Efficacy means the effect a given intervention can produce under ideal, clinically controlled circumstances regardless of costs. This efficacy, measured under ideal circumstances, normally means information from randomized controlled clinical trials. In randomized controlled clinical trials the efficacy of new health technologies is tested on carefully selected patient material, involving some tens or hundreds of patients. Since in clinical trials there are strict selection and exclusion criteria and the patients are under increased supervision, it means an idealized situation, which cannot always be reproduced in everyday practice.

Effectiveness describes the effects of health intervention in everyday practice and it also examines if the expected results have been achieved, again, regardless of costs. This everyday efficacy appears as part of daily clinical routine. Thus, this is not about hundreds of carefully selected patients of a clinical trial but authorized GPs and doctors in clinics/hospitals prescribe the drugs for several thousands or tens of thousands of patients in a country. Consequently, this patient population is not as well selected as during clinical trials. Therefore, patients' compliance is not necessarily that favourable, either.

Only after the assessment of efficacy and effectiveness come the analysis of **efficiency**, during which the results of the intervention are compared to the costs. Thus, the relationship of expenditure and efficacy/effectiveness is described. Efficiency studies also include formal health economic analyses, which are dealt with in detail in another chapter (complete and

partial health economic analyses, cost-effectiveness, cost-utility, cost-benefit, etc.). It is worth noting that in the case of health technologies where clinical efficacy or effectiveness have not been verified successfully these shortcomings cannot be substituted by health economic analyses, e.g. cost-effectiveness calculations. Conversely, it can be said that meaningful and credible health economic analyses can be carried out only in cases where convincing and credible efficacy / effectiveness data are available related to the health technology in question.

7.3. TYPES OF SCIENTIFIC EVIDENCE: GENERATING EVIDENCE

7.3.1. Types of scientific evidence

Scientific evidence known and used in healthcare appears as the results of scientific research in most cases today. These research methods mainly mean researches of an epidemiological nature. Epidemiology became the methodology of applied medical research as the subject of trials suitable for exploring empirical evidence relevant for medical practice shows the general characteristics of the subject of epidemiological research, thus it can be studied by epidemiological methods. The detailed presentation of the various types of epidemiological research is found in the epidemiological chapter. The table below illustrates the types of scientific evidence.

Table 3
Types of scientific evidence

Systematic literature review, meta-analysis
Randomized controlled trial
Cohort study
Case control study
Case series study
Case study
Expert opinion
Animal tests
Basic research, laboratory experiments

The categories used in healthcare for classifying scientific evidence almost all reach back to and evaluate the evidence types presented in the table above.

Concerning research questions the Hungarian guideline provides recommendations on what types of studies are advisable for various types of research questions. Thus, for assessing therapeutic efficacy, for example, randomized controlled trials, while for the assessment of disease burden cross-sectional studies are recommended.

Table 4 Types of scientific evidence

Question:	Optimal type of study
Therapy	Randomized controlled trial
Etiology, risk	Cohort study
Predictive medicine, prognosis	Cohort study
Diagnosis	Prospective consecutive cohort
Disease burden	Cross-sectional study
Subjective or objective phenomenon	Qualitative study

7.3.2. Levels and strength of scientific evidence

Some examples of the classification of scientific evidence are shown below. Different sources present the levels of scientific evidence in different ways. The Hungarian guidelines mentioned earlier also define the levels of the guidelines and the strength of evidence. The up-to-date medical-professional guidelines of the various areas of medicine usually state the levels and strength of evidence in the guidelines themselves. The two tables below present the evidence levels and strengths set forth within the Hungarian guidelines.

Table 5 Levels of evidence-based recommendations (guidelines)

<p>Level A recommendation</p>	<p>The recommendations are based at least on a literature review which is equivalent to level 1⁺⁺ evidence and can be well adapted to the given situation of healthcare, or are based at least on trials equivalent to level 1⁺ evidence that are well adaptable and show unambiguously similar effects.</p>
<p>Level B recommendation</p>	<p>The recommendations are based at least on trials equivalent to level 2⁺⁺ evidence that are well adaptable to the given situation of healthcare and show unambiguously similar effects; or are based on level 1⁺⁺ and 1⁺ evidence that is adaptable to the given situation of healthcare but only with reservations.</p>
<p>Level C recommendation</p>	<p>The recommendations are based at least on trials equivalent to level 2⁺ evidence that are well adaptable to the given situation of healthcare and show unambiguously similar effects; or are based on level 2⁺⁺ evidence that is adaptable to the given situation of healthcare but only with reservations.</p>
<p>Level D recommendation</p>	<p>The recommendations are based on level 2-3 evidence; or on level 2⁺ evidence that is adaptable to the given situation of healthcare but only with reservations.</p>

Table 6 Strength of scientific evidence

1++	The results come from such a high quality systematic review article or several randomized controlled trials in which the risk of systematic distortion is very low.
1+	The results come from such a well-made systematic review article or several randomized controlled trials in which the risk of systematic distortion is low.
1-	The results come from such a high quality systematic review article or several randomized controlled trials in which the risk of systematic distortion is high.
2++	The results come from the systematic review of high quality cohort or case-control trials in which the risk of systematic distortion and disturbing effects is very low, moreover, the probability of a causal relationship between the evidence and the conclusions is high.
2+	The results come from well-performed cohort or case-control trials in which the risk of systematic distortion and disturbing effects is low, and the probability of a causal relationship between the evidence and the conclusions is high.
2-	The results come from cohort or case-control trials in which the risk of systematic distortion and disturbing effects is high, and the probability that the relationship between the evidence and the conclusions is not causal is high.
3	The results come from observations without experimental arrangements (e.g. case studies, case series).
4	The results are based on professional opinion (team of specialists, research team, expert).

The evidence levels published by the Oxford Centre for Evidence-Based Medicine of the University of Oxford are summarized in the table below. Compared to the earlier Oxford scales this is greatly improved, where recommendations are made according to the questions.

Table 7 Levels of scientific evidence (CEBM)

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or n-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, n-of-1 trial with the patient you are posing the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or n-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

The above scale may be modified according to the clinical questions or problems. The figures below illustrate the levels of scientific evidence in the cases of the following types of clinical questions:

- Therapy/Prevention/Etiology/Damages
- Diagnosis
- Prognosis

Table 8 The levels of scientific evidence in the cases of different clinical questions (CEBM)

Therapy/Prevention/Etiology/Harm:

1a:	Systematic reviews (with homogeneity) of randomized controlled trials
1b:	Individual randomized controlled trials (with narrow confidence interval)
1c:	All or none randomized controlled trials
2a:	Systematic reviews (with homogeneity) of cohort studies
2b:	Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up)
2c:	"Outcomes" Research; ecological studies
3a:	Systematic review (with homogeneity) of case-control studies
3b:	Individual case-control study
4:	Case-series (and poor quality cohort and case-control studies)
5:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Diagnosis:

1a:	Systematic review (with homogeneity) of Level 1 diagnostic studies; or a clinical decision rule with 1b studies from different clinical centers.
1b:	Validating cohort study with good reference standards; or clinical decision rule tested within one clinical center
1c:	Absolute SpPins And SnNouts (An Absolute SpPin is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An Absolute SnNout is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis).
2a:	Systematic review (with homogeneity) of Level >2 diagnostic studies
2b:	Exploratory cohort study with good reference standards; clinical decision rule after derivation, or validated only on split-sample or databases
3a:	Systematic review (with homogeneity) of 3b and better studies
3b:	Non-consecutive study; or without consistently applied reference standards
4:	Case-control study, poor or non-independent reference standard
5:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Prognosis:

1a:	Systematic review (with homogeneity) of inception cohort studies; or a clinical decision rule validated in different populations.
1b:	Individual inception cohort study with > 80% follow-up; or a clinical decision rule validated on a single population
1c:	All or none case-series
2a:	Systematic review (with homogeneity) of either retrospective cohort studies or untreated control groups in randomized controlled trials.
2b:	Retrospective cohort study or follow-up of untreated control patients in a randomized controlled trial; or derivation of a clinical decision rule or validated on split-sample only
2c:	"Outcomes" research
4:	Case-series (and poor quality prognostic cohort studies)
5:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

7.4. FINDING SCIENTIFIC EVIDENCE: THE COCHRANE DATABASE

Thinking of EMB it is an obvious question to ask where this evidence can be found. Besides the various literature bibliography databases, which are discussed in other chapters of this book, the so-called Cochrane database is of paramount importance.

It was Archibald Cochrane (1909–1988), a professor of epidemiology of Scottish origin, who put forth the concept according to which it was reasonable to create a database containing clinical trials related to health technologies, because, for ethical and financial reasons, healthcare had to provide effective services. He saw the guarantee of effective and efficient services in decisions based on randomized controlled trials (RCT). That was why he initiated the systematic collection and analysis of RCTs. The ideas and work of Cochrane attracted followers first in the United Kingdom and then from the whole world. At the beginning of the 1990s the first Cochrane Centre was established in Oxford followed by the Cochrane Collaboration. The Cochrane Collaboration is an international, independent non-governmental organization, whose goal is to make precise and up-to-date information related to the efficiency of health-care interventions easily available worldwide.

Currently the Cochrane Library contains the following databases:

- The Cochrane Database of Systematic Reviews
- The Database of Abstracts of Reviews of Effects (DARE)
- The Cochrane Central Register of Controlled Trials
- The Health Technology Assessment Database
- The NHS Economic Evaluation Database

It can be seen that apart from the classic clinical trial database (The Cochrane Central Register of Controlled Trials) and the database of literature reviews (The Cochrane Database of Systematic Reviews) a health technological analytic database (The Health Technology Assessment Database) and a health economic database (The NHS Economic Evaluation Database), both treating economic aspects, are also available.

The table below illustrates the types of databases of the Cochrane Library.

Table 9 The types of databases of the Cochrane Library

The Cochrane Database of Systematic Reviews

Full-text systematic reviews and meta-analyses carried out to a common protocol and quality standard by Cochrane Collaboration researchers throughout the world. There are currently 3,625 completed reviews on the database (November 2008), with a further 1,921 protocols for works in process.

The Database of Abstracts of Reviews of Effects (DARE)

This database contains 9,025 quality-appraised abstracts of systematic reviews carried out by other researchers. Protocols and quality standards may vary but this provides a useful starting point if no appropriate Cochrane review has been carried out.

The Cochrane Central Register of Controlled Trials

All Cochrane reviews start with a comprehensive review of the literature. This database provides abstracts of all controlled studies identified by the research groups, as well as further results trawled from electronic databases. There are currently around 550,000 studies included in the register.

The Health Technology Assessment Database

Produced by the Centre for Reviews and Dissemination (CRD) at York University, this database brings together details of 7,528 health technology assessments from around the world. These reviews tend to focus on efficient use of healthcare resources and often include epidemiological and economic assessments.

The NHS Economic Evaluation Database

This also originates from the CRD and focuses purely on those reviews that evaluate the economics of healthcare interventions. It currently contains details on 24,451 such appraisals.

7.5. THE ASSESSMENT OF EVIDENCE

In the previous chapters the relevance of scientific evidence in healthcare was presented. In this chapter the modes of the assessment and practical use of evidence, including the administrative and health political aspects, are introduced.

7.5.1. Entering the market: marketing authorisation

In permitting medicines to enter the market, marketing authorisation, the guidelines for good clinical practice are as follows.

The usual goals of the marketing authorisation procedure:

- Relative harmlessness (drug safety) / Safety
- Efficacy
- The analysis, definition and possible tools of decreasing risks involved in application / Risk management

Thus, the procedure involves the evaluation of the benefit/risk balance of the application of the drug (Benefit/Risk balance).

In Hungary, similarly to the other member states of the European Economic Area, the marketing authorization of medicines may happen in four ways:

- national procedure
- decentralized procedure
- mutual recognition procedure
- centralized procedure

The national procedure affects only one country, while the decentralized procedure, the mutual recognition procedure and the centralized procedure affect more than one country. In the European Union the European Medicines Agency is responsible for marketing authorisation procedures, while in the United States the Food and Drug Administration (FDA).

Downing et al. investigated the 188 new active substances authorized by the FDA between 2005 and 2012, in 206 indications and on the basis of 448 clinical trials. In these trials the primary outcomes are surrogate endpoints in 91 indicators (45.3%), clinical endpoints in 67 indicators (33.3%) and clinical scales in 36 indicators (17.9%). It is interesting that in many of the cases surrogate endpoints were used instead of clinical endpoints.

Table 10 The trials of the products approved of by the FDA between 2005 and 2012: comparator and endpoint (Downing et al., 2014)

Table 2. Design of Pivotal Efficacy Trials Providing the Basis for Approval of Novel Therapeutic Agents by the US Food and Drug Administration Between 2005 and 2012, Stratified by Therapeutic Agent and Indication Characteristics

Agent/Indication Characteristic (Pivotal Trials)	No. (%) [95% CI]							
	Randomized	Double-Blinded	Comparator			End Point		
			Active	Placebo	None	Surrogate Outcome	Clinical Outcome	Clinical Scale
All (N = 448)	400 (89.3) [86.4-92.2]	356 (79.5) [75.7-83.2]	143 (31.9) [27.6-36.3]	247 (55.1) [50.5-59.8]	58 (12.9) [9.8-16.1]	219 (48.9) [44.2-53.5]	130 (29.0) [24.8-33.2]	99 (22.1) [18.2-26.0]
Therapeutic area								
Cancer (n = 55)	26 (47.3) [33.7-60.9]	15 (27.3) [15.1-39.4]	10 (18.2) [7.7-28.7]	16 (29.1) [16.7-41.5]	29 (52.7) [39.1-66.3]	46 (83.6) [73.5-93.7]	9 (16.4) [6.3-26.5]	0
Infectious disease (n = 57)	53 (93.0) [86.1-99.8]	45 (78.9) [68.0-89.9]	39 (68.4) [56.0-80.9]	13 (22.8) [11.6-34.0]	5 (8.8) [1.2-16.3]	33 (57.9) [44.7-71.1]	24 (42.1) [28.9-55.3]	0
Cardiovascular disease, diabetes mellitus, hyperlipidemia (n = 73)	72 (98.6) [95.9-100.0]	68 (93.2) [87.2-99.1]	26 (35.6) [24.4-46.9]	45 (61.6) [50.2-73.1]	2 (2.7) [0.0-6.6]	62 (84.9) [76.5-93.3]	11 (15.1) [6.7-23.5]	0
Neurology (n = 38)	38 (100.0) [100.0-100.0]	38 (100.0) [100.0-100.0]	6 (15.8) [3.6-27.9]	30 (78.9) [65.4-92.5]	2 (5.3) [0.0-12.7]	0	25 (65.8) [50.0-81.6]	13 (34.2) [18.4-50.0]
Dermatology (n = 29)	27 (93.1) [83.3-100.0]	22 (75.9) [59.3-92.4]	5 (17.2) [2.6-31.9]	20 (69.0) [51.1-86.9]	4 (13.8) [0.4-27.1]	5 (17.2) [2.6-31.9]	15 (51.7) [32.4-71.1]	9 (31.0) [13.1-48.9]
Autoimmune/musculoskeletal (n = 36)	36 (100.0) [100.0-100.0]	34 (94.4) [86.6-100.0]	11 (30.6) [14.7-46.3]	25 (69.4) [53.6-85.3]	0	6 (16.7) [3.9-29.5]	2 (5.6) [0.0-13.4]	28 (77.8) [63.5-92.0]
Psychiatry (n = 43)	43 (100.0) [100.0-100.0]	43 (100.0) [100.0-100.0]	19 (44.2) [28.7-60.0]	24 (55.8) [40.3-71.3]	0	5 (11.6) [1.6-21.6]	7 (16.3) [4.8-27.8]	31 (72.1) [58.1-86.1]
Other (n = 117)	105 (89.7) [84.2-95.3]	91 (77.8) [70.1-85.4]	27 (23.1) [15.3-30.8]	74 (63.2) [54.4-72.1]	16 (13.7) [7.4-20.0]	62 (53.0) [43.8-62.2]	37 (31.6) [23.1-40.2]	18 (15.4) [8.7-22.0]
P value	<.001	<.001		<.001			<.001	

According to the study of Downing and his colleagues the FDA authorized the therapeutic agents on the basis of 2 clinical trials on average. The average number of patients in a trial in the intervention group was 445. At the same time, huge differences were found between the individual indications / patients' groups. In the case of products for tumour, in an average clinical trial an intervention group of 277 patients took the new medicine. In the case of cardiovascular clinical pictures, however, in an average of 3 clinical trials intervention groups of 2291 patients per trial took the new medicine.

Table 11 The number of products approved of by the FDA between 2005 and 2012 and the number of trials and patients (Downing et al., 2014)

Table 4. Number of Aggregated Pivotal Efficacy Trials and Total Number of Patients Providing the Basis for Indication-Level Approval of Novel Therapeutic Agents by the US Food and Drug Administration Between 2005 and 2012, Stratified by Therapeutic Agent and Indication Characteristics^a

Agent/Indication Characteristic (Indications)	Median (IQR), No.			
	Pivotal Efficacy Trials	Patients in Aggregated Pivotal Efficacy Trials		Total Safety Population ^b
		Overall	Intervention Group	
All indications (N = 201)	2.0 (1.0-2.5)	760 (270-1550)	445 (169-936)	1143 (503-2600)
Therapeutic area				
Cancer (n = 41)	1.0 (1.0-1.0)	397 (180-634)	277 (159-414)	511 (295-1100)
Infectious disease (n = 27)	2.0 (2.0-2.0)	1171 (763-1408)	605 (462-817)	1408 (840-1979)
Cardiovascular disease, diabetes mellitus, hyperlipidemia (n = 23)	3.0 (1.0-5.0)	3645 (1446-5942)	2291 (832-3947)	3422 (1579-6570)
Neurology (n = 17)	2.0 (2.0-3.0)	1088 (448-1394)	661 (279-877)	2315 (1729-3145)
Dermatology (n = 15)	2.0 (1.0-2.0)	374 (233-1005)	187 (127-376)	1193 (1048-2228)
Autoimmune/musculoskeletal (n = 13)	2.0 (2.0-3.0)	1209 (289-2893)	804 (223-1906)	1955 (379-3233)
Psychiatry (n = 10)	4.0 (2.0-5.5)	1492 (947-3000)	878 (417-1812)	3290 (1596-4099)
Other (n = 55)	2.0 (1.0-2.0)	418 (105-1608)	238 (78-968)	700 (296-1781)
P value	<.001	<.001	<.001	<.001

7.5.2. Clinical guidelines

After marketing authorisation new medical technologies and medicines generally appear in medical-professional guidelines first. Clinical guidelines contain the current diagnostic and therapeutic procedures of a given area. Freshly authorised products are usually added to therapeutic procedures when the relevant guideline is next updated.

In Hungary clinical guidelines are prepared by medical-professional organizations (professional councils, societies) and they are published following approval by the ministry responsible for healthcare.

It poses an interesting problem when a new medical technology, e.g. a new medicine, is added to the clinical guidelines but is not available to patients due to a lack of subsidization by the social security and it cannot be paid for from their own pockets.

Concerning such cases the National Health Insurance Fund of Hungary published a special communiqué. According to section 9. § (2) of the decree of the Ministry of Human Capacities No 18/2013. (III. 5.) about the standardized rules for the development and construction of examination and therapeutic procedures and conducting professional negotiations about them: “The new healthcare professional guideline is sent to the OEP by the GYEMSZI (ÁEEK). The OEP shall make a statement on which of the recommendations of the healthcare professional guideline do not become procedures involved in public financing at the time of the finalization of the healthcare professional guideline. The document related to that shall be published on the official website of the OEP and shall also be accessible via the website of healthcare professional guidelines.”

Complying with its legal obligations the OEP provides information about the procedures included in the individual healthcare professional guidelines which do not receive financing or subsidization from the Health Insurance Fund.

7.5.3. Subsidization by the Social Security: HTA

The next stage of the assessment of scientific evidence -following the marketing authorisation and the guidelines- is upon inclusion in subsidization by the social security. Although the evidence is already evaluated during marketing authorisation, the funding organizations assess it again according to slightly different criteria and considerations.

The inclusion of medicines, medical accessories and healthcare (hospital) technologies in subsidization by the social security is regulated in detail by law. The Hungarian legislation related to the individual areas of healthcare:

- medicines: ESzCsM Decree No. 32/2004. (IV. 26.) on the criteria of admission in the scope of social security subsidization of authorized medicines and dietary supplements for special dietary needs, and the modification of admission or subsidization
- Medical accessories: Ministry of Health Decree No. 14/2007. (III. 14.) on the admission in the scope of social security subsidization of medical accessories and their subsidized ordering, distribution, repair and renting
- Health technologies: Gov. Decree No. 180/2010. (V. 13.) about the principles, criteria and detailed regulation of admission in the scope of social security subsidization of health technologies, and the modification and revision of the list of admitted technologies and Ministry of Health Decree 28/2010. (V. 12.) about the professional criteria and sector political priorities and the administration service fees payable for the individual procedures related to admission in the scope of social security subsidization of health technologies used in curative-preventive procedures.

In the assessment of efficacy absolute and relative efficacies are measured. In the case of absolute efficacy there is no comparator, i.e. the product examined is not compared to anything. A comparator could be a placebo, any alternative treatment method and the best alternative treatment method, which already takes us to relative efficacy.

Another assessment axis assesses new products in relation to efficacy and effectiveness. As you could see in the definitions, efficacy represents a value under the ideal circumstances of clinical trials, while efficiency shows effectiveness under real world circumstances.

In the figure below the types of trials are illustrated along the two axes (randomized controlled study, case control study, analysis of health insurance data, etc.).

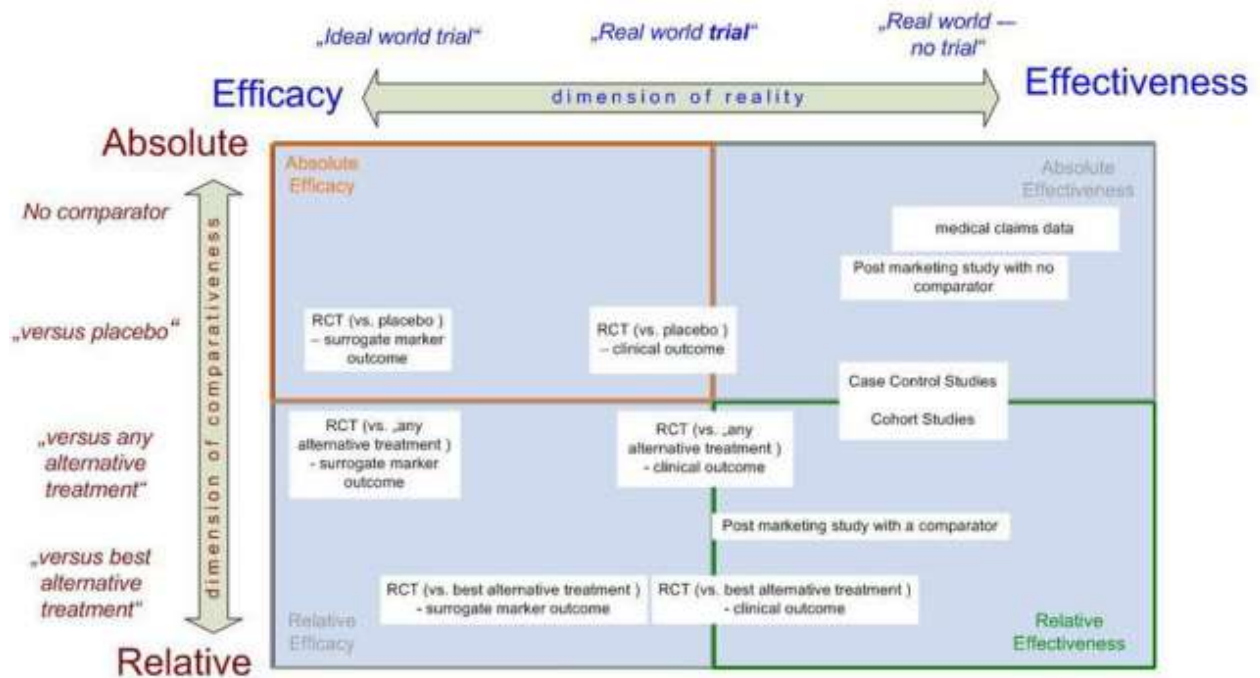
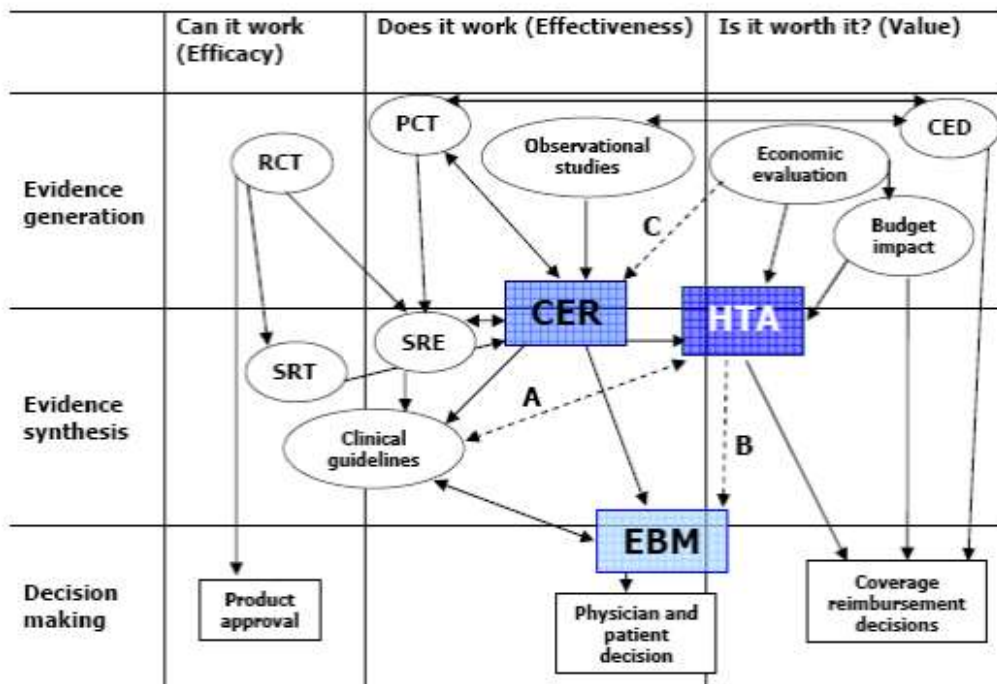


Figure 14 Efficacy and effectiveness (High Level Pharmaceutical Forum)

The detailed pattern of the generation and assessment of evidence is well illustrated by Luce et al. in the following figure.

The vertical axis shows the generation and synthesis of evidence and decision-making, while the horizontal axis illustrates the dimensions of efficacy, effectiveness, and economic evaluation. The figure points out the place of clinical trials and health economic analyses in the process very well.

Figure 3. Redefined relationships of evidence processes



Abbreviations: CED= coverage with evidence development; CER=comparative effectiveness research; EBM=evidence based medicine; HTA=health technology assessment; PCT=pragmatic clinical trial; RCT=randomised controlled trial; SRE= systematic review of evidence; SRT= systematic review of trials.
Note: Solid lines indicate clear relationships, and dotted lines indicate disputed relationships. White rectangles represent decision processes, and circles and ovals represent all other evidence activities, except for the coloured rectangles, which are reserved for EBM, HTA, and CER.
Source: Luce BR, Drummond M, Jönsson B, Neumann PJ, Schwartz JS, Siebert U, Sullivan SD. EBm, HTA, and CER: clearing the confusion. *Milbank Q.* 2010 Jun;88(2):256-76.

Figure 15 The generation and assessment of evidence (Luce et al. *Milbank Q.* 2010;88(2):256-76.)

As a main rule of the assessment of scientific evidence it can be said that organizations responsible for funding (like the National Health Insurance Fund in Hungary) evaluate scientific evidence more rigorously than marketing authorisation authorities.

In the last few years the non-inferiority design, by which it is shown that the product being tested is not less effective than the already authorized product in the market, has become more and more common in the practice of clinical trials. Although it is enough for marketing authorisation, it is not necessarily sufficient for decisions on the funding of subsidization.

In their article Kolasa et al. examined what the main reasons were for rejecting requests for subsidization funded by the social security in Poland. Surprisingly, the main reason for the rejection of subsidization requests was not the price of a medicine or its cost-effectiveness.

In the table below it is presented that the most common reason for rejection (in 81% of all cases) was the insufficient clinical data or weak efficacy /safety. Inacceptable cost-

effectiveness indices lead to a negative decision on subsidization requests in only 14% of the cases.

Table 1
Drug technologies with HTA recommendations issued in years 2007–2009.

	Total		Appraised and reimbursed		Appraised and not reimbursed	
	Total	as %	Total	as %	Total	as %
<i>Negative HTA recommendations</i>						
Number of HTA	63	100%	4	10%	59	90%
Based on clinical reasons:						
Total	51	81%	4	12%	47	88%
Insufficient clinical data	32	51%	3	13%	29	88%
Poor efficacy or safety	19	30%	1	11%	18	89%
Based on non-clinical reasons:						
Total	12	20%	0	0%	12	100%
Unacceptable cost-effectiveness ratio	9	14%	0	0%	9	100%
Unacceptable BI	2	3%	0	0%	2	100%
Risk of off-label use	1	3%	0	0%	1	100%
<i>Positive HTA recommendations</i>						
Number of HTA	88	100%	30	35%	58	65%
HTA recommendation with:						
Major restriction	33	100%	14	43%	19	57%
Minor restrictions	40	100%	11	27%	29	73%
Without additional restrictions	15	100%	5	33%	10	67%

Source: Own calculations based on results from www.aotm.gov.pl.
Statistical significance was not calculated. It is only descriptive statistics.

Figure 16 The categories of health economic analyses (Kolasa et al. 2011)

7.5.4. Protocols of financing

According to the glossary of the Health Strategic Research Institute, the protocols of financing elaborate within the sectoral professional regulations with what kind of professional content and in what procedure a given intervention may be used at the expense of public financing. Thus, the protocols of funding do not overwrite the professional protocols but are of a restrictive nature: they appoint the technologies and procedures that may be provided at the expense of public funding within the latter.

The table below illustrates the effective protocols of financing.

Financing protocol of the diagnostics and treatment of clear cell kidney tumours
Financing protocol of the treatment of chronic myeloid leukaemia
The diagnostics and therapy of chronic hepatitis caused by the Hepatitis C virus
Financing protocol of the diagnostics and therapy of chronic hepatitis caused by the Hepatitis C virus
Financing protocol of the secondary prevention of bone fractures in women caused by osteoporosis
Financing protocol of the primary prevention of bone fractures in women caused by osteoporosis
Financing protocol of the diagnostics and therapy of arthritis sporiatica
Financing protocol of the diagnostics and therapy of spondylitis ankylopoetica
Financing protocol of the diagnostics and therapy of juvenile idiopathic arthritis
Financing protocol of the diagnostics and therapy of rheumatoid arthritis
Financing protocol of the diagnostics and therapy of plaque psoriasis
Financing protocol of the diagnostics and therapy of colitis ulcerosa disease
Financing protocol of the diagnostics and therapy of Crohn's disease in children
Financing protocol of the diagnostics and therapy of fistulizing Crohn's disease in adults
Financing protocol of the diagnostics and therapy of luminal Crohn's disease in adults
Financing protocol of the diagnostics and therapy of chronic hepatitis caused by the Hepatitis B virus
Financing protocol of the diagnostics and therapy of Parkinson's disease
Financing protocol of the treatment of anaemia caused by chemotherapy
Financing protocol of the diagnostics and treatment of non-clear cell kidney tumours
Financing protocol of the treatment of myeloma multiplex

Table 12 Effective OEP financing protocol (OEP, May 2015)

7.6. EBM AND HEALTH POLICY

As seen above, in decision-making it is the scientific evidence and the social preferences that are evaluated. The preference of social interrelations occurs in traditional political decision-making. The preference of evidence, on the other hand, strengthens evidence-based decision-making. As shown in the figure below, in an ideal situation social aspects and scientific evidence are both assessed.

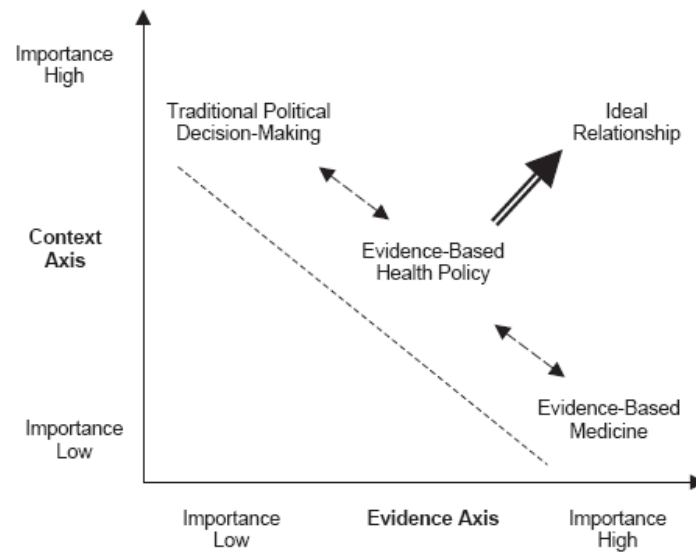


Fig. 1. Axes of evidence-based decision-making.

Figure 17 Evidence-based health policy as a function of EBM and policy (Dobrow et al., 2004)

The significance of scientific evidence is paramount not only in clinical practice but also in health policy decision-making. In healthcare systems struggling with the shortage of resources the assessment of scientific evidence plays a major role in the justification of decisions on the allocation of funds.

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4. 28/2010. (V. 12.) EüM rendelet a gyógyító-megelőző eljárások során alkalmazott egészségügyi technológiák egészségbiztosítási finanszírozásba történő befogadásához kapcsolódó eljárás során alkalmazandó szakmai szempontrendszeréről és szakmapolitikai prioritásokról, valamint a befogadásához kapcsolódó egyes eljárásokért fizetendő igazgatási szolgáltatási díjakról
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8. E BIBLIOGRAPHIC DATA OF SCIENTIFIC RESULTS (I. BONCZ, I. ÁGOSTON)

8.1. INTERNATIONAL BIBLIOGRAPHIC DATABASES

8.1.1. Pubmed / Medline

In 1879 the Index Medicus scientific bibliographic index was first published in the United States upon the initiative of John Shaw Billings, the head of the Library of the Surgeon General's Office of the US Army (Armed Forces Medical Library). The publication appeared in print monthly with a hiatus between 1899 and 1902. In 1927 the Index Medicus was amalgamated with the publication of the American Medical Association Quarterly Cumulative Index to Current Literature (QCICL) and was published by the AMA as the Quarterly Cumulative Index Medicus (QCIM) until 1956. Between 1960 and 2004 the National Library of Medicine published it under the name Index Medicus/Cumulated Index Medicus (IM/CIM). The last printed copy appeared in December 2004

The colleagues of the National Library of Medicine began designing the computer-based database in 1957. That was the MEDLARS (Medical Literature Analysis and Retrieval System) system, for whose realisation the tender was won by the General Electric Company out of 72 bidders. The library (NLM) received the computer needed for the operation of the system, a Minneapolis-Honeywell 800, in March 1963. The online version of the system appeared at the end of 1971: MEDLINE ("MEDLARS Online"). The terms (keywords) used for indexing and searching were first published in 1960 under the name of Medical Subject Headings (MeSH).

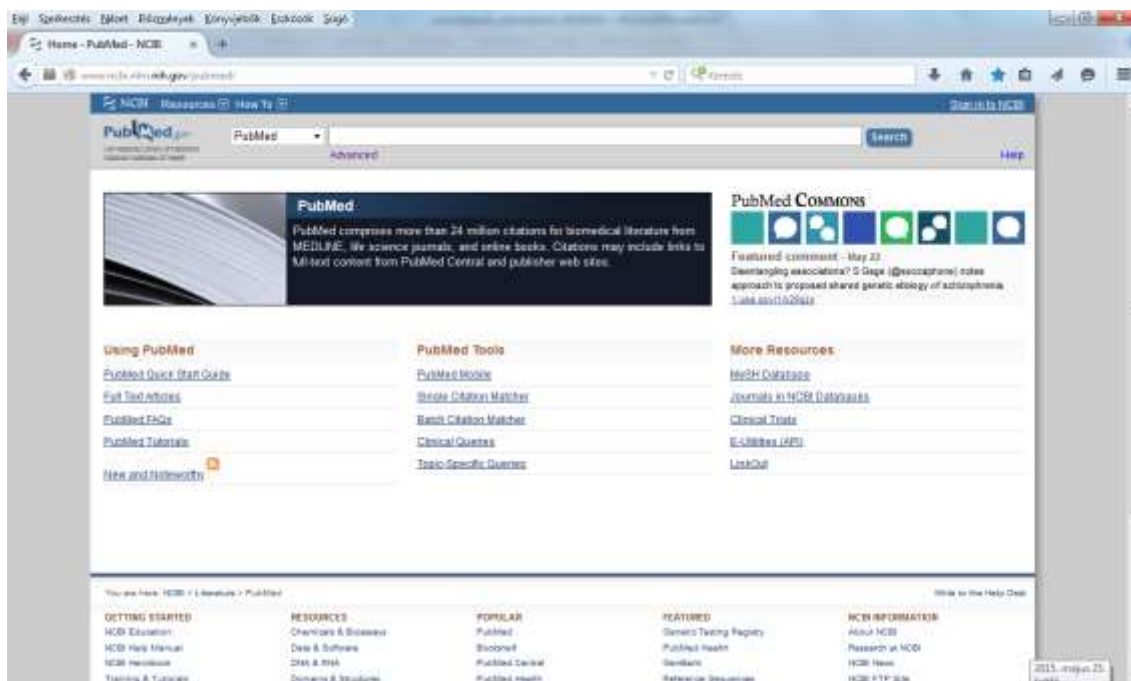


Figure 10
Pubmed / Medline online search interface

Today the Pubmed / Medline system is the leading electronic bibliographic database in the area of medicine and health science. Thanks to its wide coverage, large temporal scope and easy access it is of fundamental significance to researchers.

It is worth noting that the Pubmed / Medline system is accessible free of charge via the Internet up to the present day (<http://www.ncbi.nlm.nih.gov/pubmed/>). That is how it provides an opportunity for the dissemination of scientific results and the development of their access. The breakthrough took place in 1997 when the MEDLINE database was made accessible via Pubmed for free. At that time the database contained 9 million records.

In the Internet interface of Pubmed / Medline one can search among the publications. In the following pages examples are shown for various basic search options, such as searching by authors or keywords.

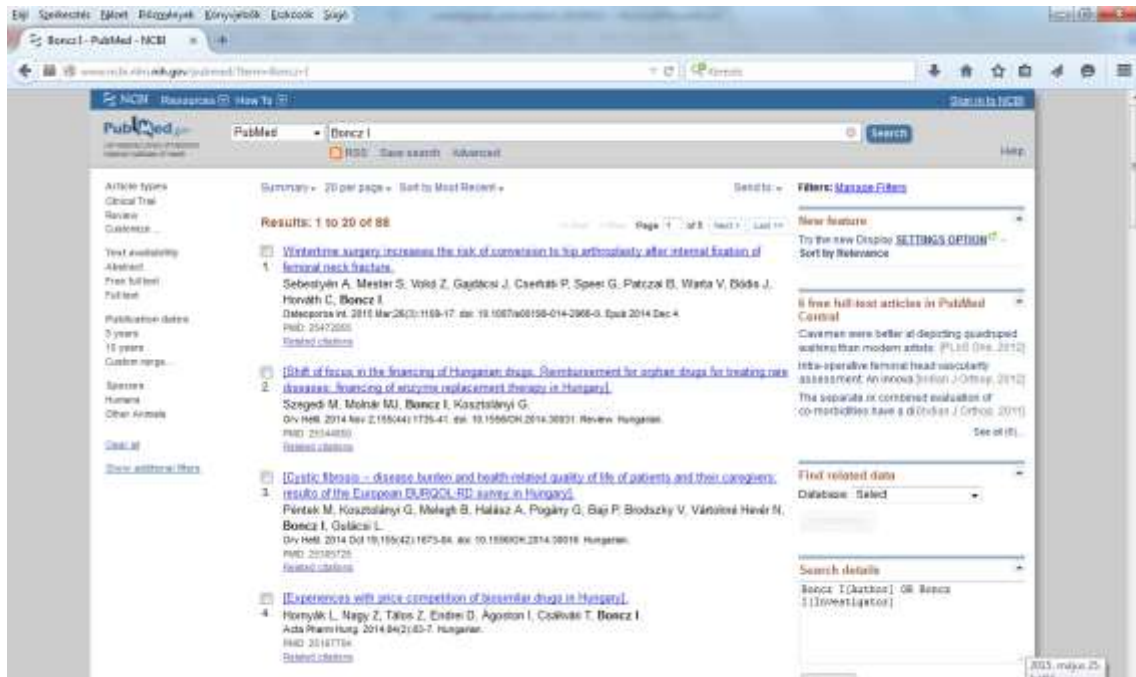


Figure 11

The results page of the Pubmed / Medline online search interface (search term: Boncz I)

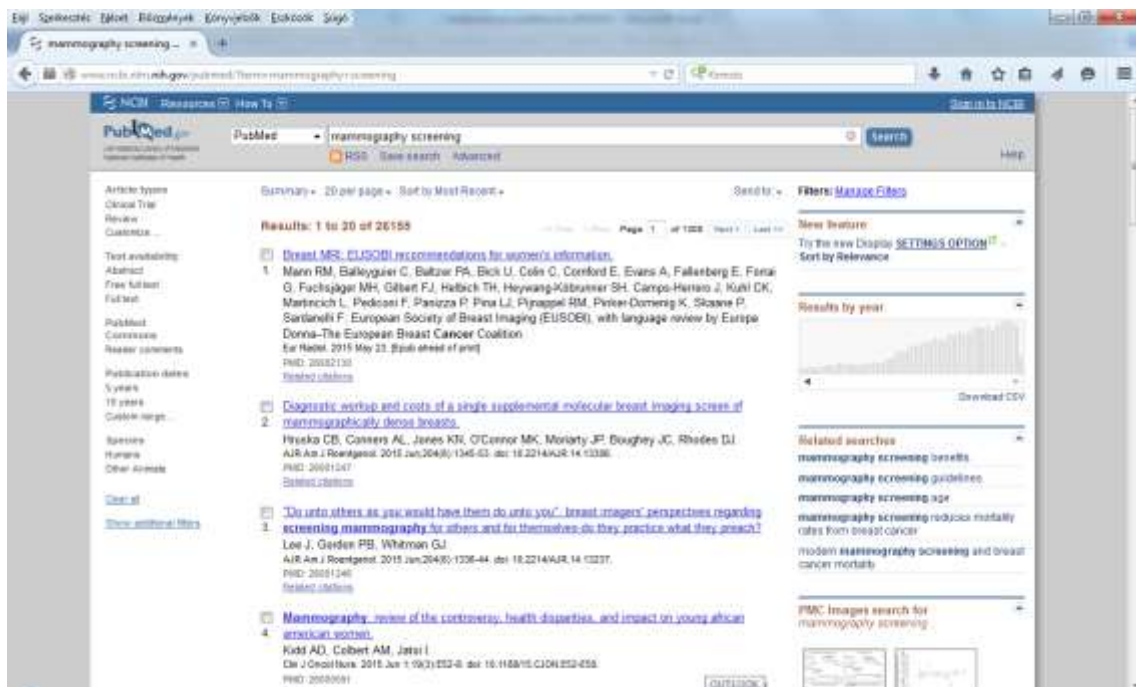


Figure 12

The results page of the Pubmed / Medline online search interface (search term: mammography screening)

In searching by key concepts there is a possibility to narrow down the search by combining search terms, otherwise it often happens that simple searches with just one-two search terms produce very many results. In the mammography search above, for example, more than 26 000 results for “mammography screening” were found, which is practically impossible to handle. Narrowing down the search to the rates of attendance (“mammography screening AND attendance”) only 281 results are displayed. If one narrows it down further by searching for publications on the rates of mammography screening attendance in Hungary (“mammography screening AND attendance AND Hungary”), there are only 5 results. And these 5 publications can be accessed and handled without any problem.



Figure 13

The results page of the Pubmed / Medline online search interface (search term: mammography screening AND attendance)



Figure 14

The results page of the Pubmed / Medline online search interface (search term: mammography screening AND attendance AND Hungary)

The summarized results of the search strategies related to mammography screening are illustrated by the table below. The addition of search terms (key concepts) results in a decrease, narrowing down of the number of items found.

Table 8

The number of search results of the Pubmed / Medline search strategies presented

Keywords for search	Number of results
mammography screening	26,150
mammography screening AND attendance	281
mammography screening AND attendance AND Hungary	5

The detailed results of a Pubmed / Medline search are illustrated by the table below. Of the data of the publication the following are available in the Internet interface:

- title
- authors
- cooperating partners
- data of publication (journal)
- abstract
- identification
- type of publication
- list of keywords (MeSH)
- research grant support
- access to full-text
-

Table 9

Pubmed / Medline sample of a search result

[Ann Intern Med.](#) 2013 Jul 2;159(1):1-12. doi: 10.7326/0003-4819-159-1-201307020-00003.

Salicylate (salsalate) in patients with type 2 diabetes: a randomized trial.

[Goldfine AB](#)¹, [Fonseca V](#), [Jablonski KA](#), [Chen YD](#), [Tipton L](#), [Staten MA](#), [Shoelson SE](#); [Targeting Inflammation Using Salsalate in Type 2 Diabetes Study Team](#).

[Collaborators \(27\)](#)

[Author information](#)

Abstract

BACKGROUND:

Short-duration studies show that salsalate improves glycemia in type 2 diabetes mellitus (T2DM).

OBJECTIVE:

To assess 1-year efficacy and safety of salsalate in T2DM.

DESIGN:

Placebo-controlled, parallel trial; computerized randomization and centralized allocation, with patients, providers, and researchers blinded to assignment. (ClinicalTrials.gov: [NCT00799643](#)).

SETTING:

3 private practices and 18 academic centers in the United States.

PATIENTS:

Persons aged 18 to 75 years with fasting glucose levels of 12.5 mmol/L or less (≤ 225 mg/dL) and hemoglobin A1c (HbA1c) levels of 7.0% to 9.5% who were treated for diabetes.

INTERVENTION:

286 participants were randomly assigned (between January 2009 and July 2011) to 48 weeks of placebo (n = 140) or salsalate, 3.5 g/d (n = 146), in addition to current therapies, and 283 participants were analyzed (placebo, n = 137; salsalate, n = 146).

MEASUREMENTS:

Change in hemoglobin A1c level (primary outcome) and safety and efficacy measures.

RESULTS:

The mean HbA1c level over 48 weeks was 0.37% lower in the salsalate group than in the placebo group (95% CI, -0.53% to -0.21%; P < 0.001). Glycemia improved despite more reductions in concomitant diabetes medications in salsalate recipients than in placebo recipients. Lower circulating leukocyte, neutrophil, and lymphocyte counts show the anti-inflammatory effects of salsalate. Adiponectin and hematocrit levels increased more and fasting glucose, uric acid, and triglyceride levels decreased with salsalate, but weight and low-density lipoprotein cholesterol levels also increased. Urinary albumin levels increased but reversed on discontinuation; estimated glomerular filtration rates were unchanged.

LIMITATION:

Trial duration and number of patients studied were insufficient to determine long-term risk-benefit of salsalate in T2DM.

CONCLUSION:

Salsalate improves glycemia in patients with T2DM and decreases inflammatory mediators. Continued evaluation of mixed cardiorenal signals is warranted.

Summary for patients in

- [Summaries for patients. Salsalate for type 2 diabetes mellitus.](#) [Ann Intern Med. 2013]

PMID:

23817699

[PubMed - indexed for MEDLINE]

PMCID:

PMC4128629

[Free PMC Article](#)

- - Images from this publication. [See all images \(4\)](#) [Free text](#)

Table 10

Pubmed / Medline sample of a search result (cont.)

Publication Types, MeSH Terms, Substances, Secondary Source ID, Grant Support

Publication Types

- Clinical Trial
- Clinical Trial, Phase II
- Multicenter Study
- Randomized Controlled Trial
- Research Support, N.I.H., Extramural

MeSH Terms

- Adolescent
- Adult
- Aged
- Anti-Inflammatory Agents, Non-Steroidal/administration & dosage*
- Anti-Inflammatory Agents, Non-Steroidal/adverse effects
- Blood Glucose/metabolism
- Diabetes Mellitus, Type 2/blood
- Diabetes Mellitus, Type 2/drug therapy*
- Diabetes Mellitus, Type 2/physiopathology
- Female
- Hemoglobin A, Glycosylated/metabolism
- Humans
- Kidney/drug effects
- Kidney/physiopathology
- Male
- Middle Aged
- Salicylates/administration & dosage*
- Salicylates/adverse effects
- Single-Blind Method
- Young Adult

Substances

- Anti-Inflammatory Agents, Non-Steroidal
- Blood Glucose
- Hemoglobin A, Glycosylated
- Salicylates
- salicylsalicylic acid

Secondary Source ID

- [ClinicalTrials.gov/NCT00799643](https://clinicaltrials.gov/NCT00799643)

Grant Support

- P30 DK036836/DK/NIDDK NIH HHS/United States
- P30 DK03836/DK/NIDDK NIH HHS/United States
- P30 DK063491/DK/NIDDK NIH HHS/United States
- P50 HL083813/HL/NHLBI NIH HHS/United States
- P50 HL83813/HL/NHLBI NIH HHS/United States
- RC4 DK090792/DK/NIDDK NIH HHS/United States
- U01 DK074556/DK/NIDDK NIH HHS/United States
- U01 DK74556/DK/NIDDK NIH HHS/United States
- UL1 TR000124/TR/NCATS NIH HHS/United States
- UL1 TR000454/TR/NCATS NIH HHS/United States

LinkOut - more resources

Full Text Sources

- Silverchair Information Systems
- EBSCO
- Europe PubMed Central - Author Manuscript
- Ovid Technologies, Inc.
- PubMed Central - Author Manuscript
- PubMed Central Canada - Author Manuscript

Medical

- ClinicalTrials.gov
- Diabetes - Genetic Alliance
- Diabetes, Type 2 - Genetic Alliance
- Diabetes Type 2 - MedlinePlus Health Information

The fact that 40% of the publications that appear in the journals indexed by the Pubmed / Medline system are published in the United States and 93% of the publications are in English is often mentioned as a distortion of the system. This 'Anglo-Saxon' bias is also found in other databases; unfortunately, it is not a unique feature of Pubmed / Medline.

The database contains approximately 24 million records at present, and it is developing rapidly. The 20 millionth item was recorded in the Medline system on 27 July 2010.

8.1.2. Cumulative Index to Nursing and Allied Health Literature (CINAHL)

The Cumulative Index to Nursing and Allied Health Literature (CINAHL) is the leading bibliographic database of nursing and its related disciplines. It contains around 50 areas of nursing.

At present it indexes 5 300 journals, 1 400 of which are accessible in their full-text versions. The database of 4.5 million records is available back to 1937.

The CINAHL database is also available on the Internet (<https://health.ebsco.com/products/cinahl-complete>), but access is subject to subscription. Concerning bibliographic databases subject to subscription it is important to mention the system of Electronic Information Provision (EISZ).

The search interface of the CINAHL also allows search by authors and keywords.



Figure 15
The former independent CINAHL website

8.1.3. Web of Science

The Web of Science (WoS) is the bibliographic database of the ISI (Institute for Scientific Information, Thomson Reuters). It contains approximately 12 000 journals, 50 000 books and 160 000 conference proceedings. These references are found collected in 7 large databases.

- Conference Proceedings Citation Index: more than 172,000 conference proceedings from 1990 to the present day.
- Science Citation Index Expanded: more than 8,500 prestigious international journals from 150 disciplines covering the period from 1900 to the present day.
- Social Sciences Citation Index: more than 3,000 social sciences journals covering the period from 1900 to the present day.
- Arts & Humanities Citation Index: more than 1,700 humanities and arts journals from 1975 to the present day. It also contains 250 major scientific and social sciences journals.
- Index Chemicus: more than 2.6 million records from 1993 up to the present day.
- Current Chemical Reactions: more than 1 million chemical reactions beginning from 1986. The INPI archive for the 1840-1985 period is also available here.
- Book Citation Index: more than 60,000 selected books starting from 2005.

It covers the following major sciences and disciplines: psychology, sociology, mathematics, physics, chemistry, biology, medicine, IT and computing, linguistics and literature.

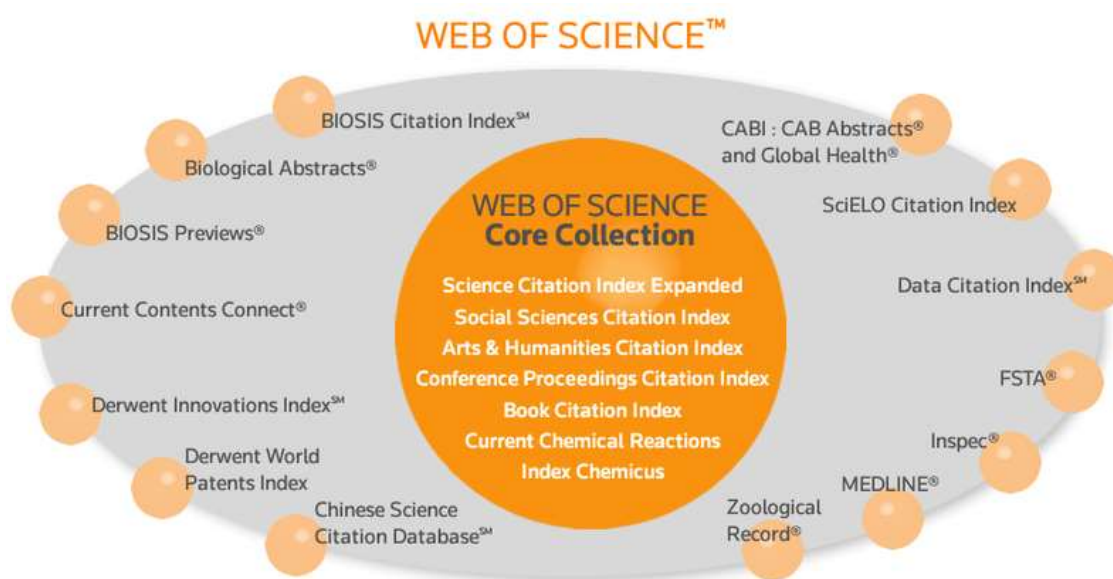


Figure 16

The structure of the Web of Science (Thomson Reuters)

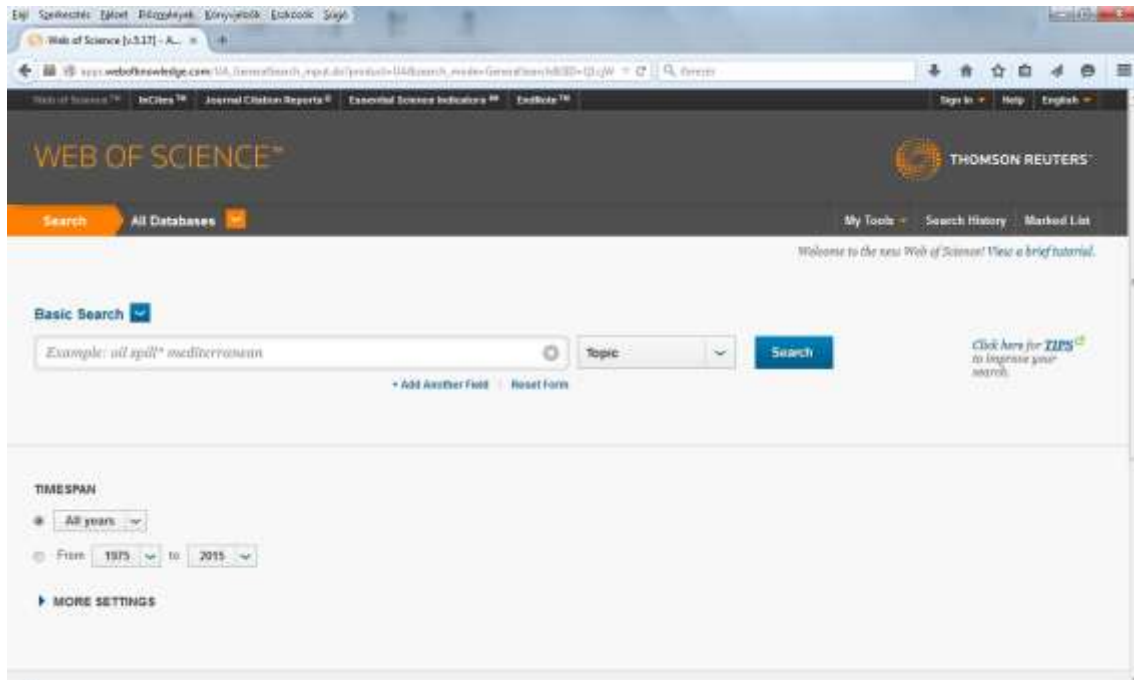


Figure 17

The opening page of the Web of Science (Thomson Reuters)

Searching by author is greatly facilitated by the so-called AUTHOR IDENTIFIERS in the Web of Science. Author identifiers provide a picture of the scientific activities of the individual authors by the Researcher ID (www.researcherID.com) system.

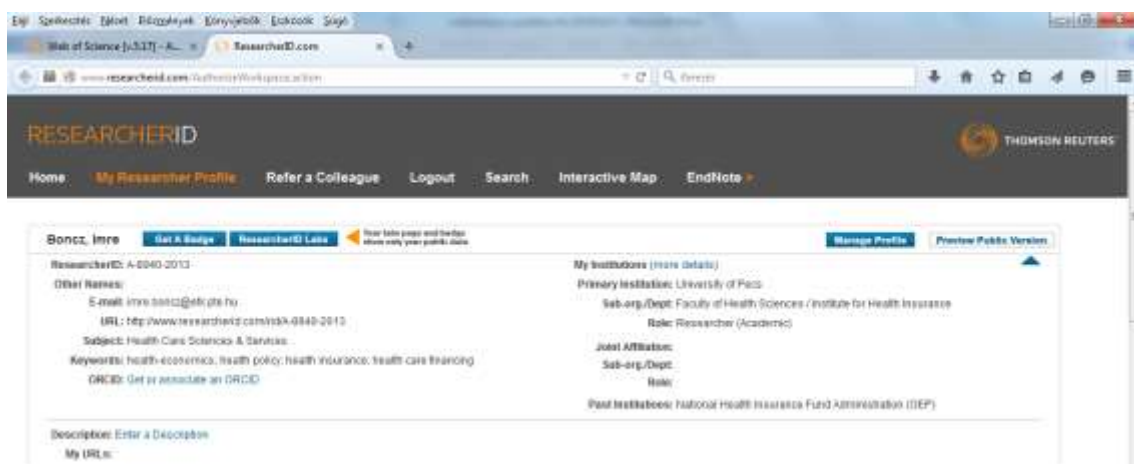


Figure 18

The opening page of the ResearcherID (Thomson Reuters)

8.1.4. Scopus

This is the main bibliographic database of the Elsevier company, which is also used as a starting database by numerous other platforms (e.g. Embase). The database contains more than 22,000 publications, among others 20,800 peer-reviewed journals (with 2,600 open access journals), 367 professional publications, 400 series of books and 6.4 million conference proceedings. At present the database contains more than 54 records, 33 million of which are later than 1996, while the other 21 million are from the period 1823-1996.

As a unique feature the database also contains 25 million patent records from 5 of the world's great patent offices:

- US Patent & Trademark Office,
- European Patent Office,
- Japan Patent Office,
- World Intellectual Property Organization,
- UK Intellectual Property Office.

Apart from its bibliographic aspects the Scopus database is also suitable for preparing scientometrical analyses.

By the "Author Identifier" it strengthens the identification and linking of authors and publications. It is especially important since certain authors with identical names (Tóth, Schmidt, Johns, Li, etc.) are difficult to differentiate. However, the names of authors with rare names may also be misspelt.

The "Affiliation Identifier" automatically identifies and links organizations and all their research results. That means that the scientific achievements of various universities and research institutions become analysable, assessable and comparable.

The "Journal Analyser" provides a comprehensive overview of the activities of individual journals.

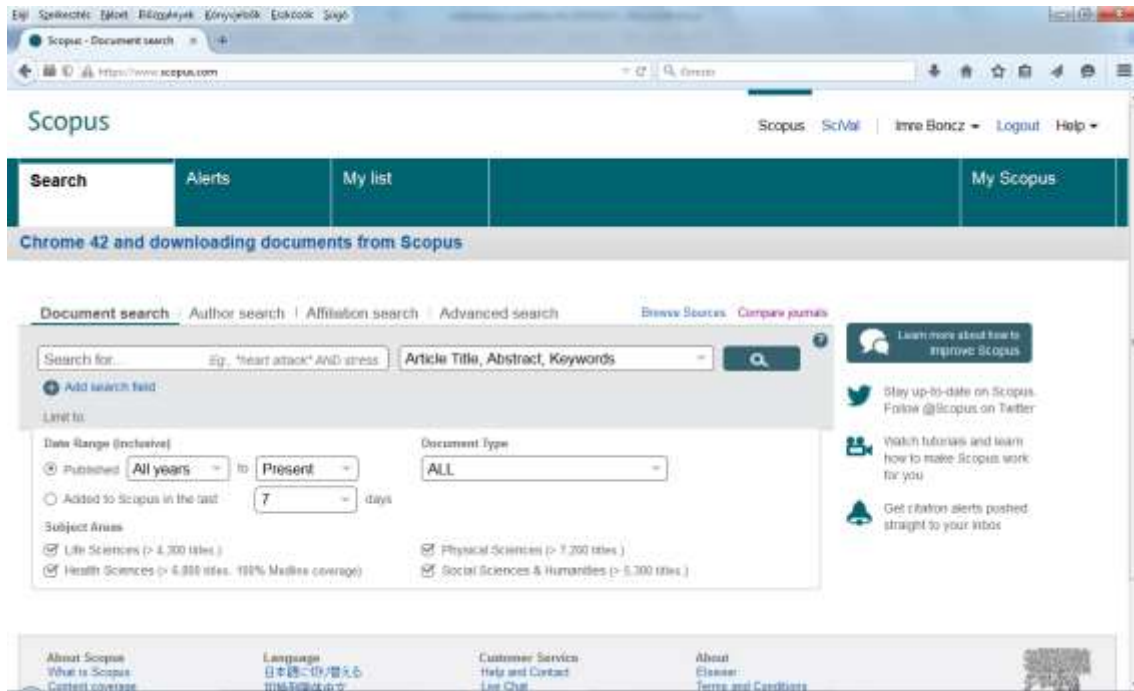


Figure 19

The website of the Scopus database (Elsevier)

For the identification of authors there is an identification number, which makes the identification of authors easier, here too. The results page of the author search is illustrated by the figure below. In the case of searching for an author one finds not only the publications of the author but also his/her affiliation, subject area, co-authors, citations and Hirsch index among the results. In a yearly breakdown you can also see the number of the authors' publications and the citations received for each of them displayed in a graph.

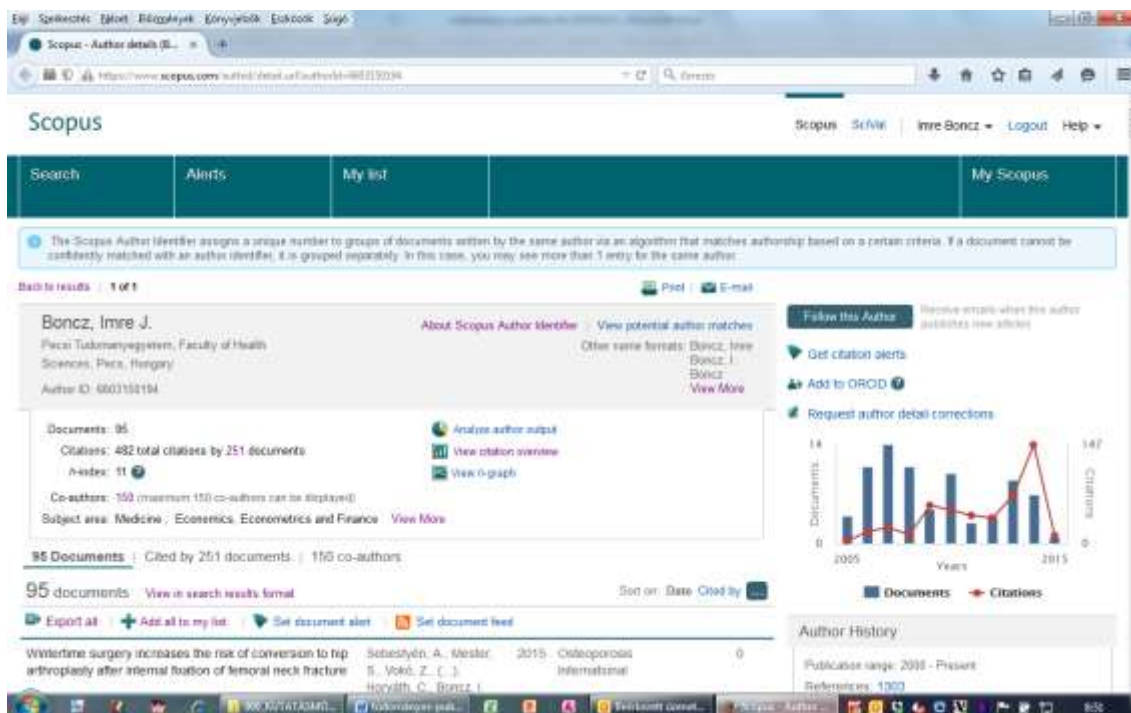


Figure 20

The results page of the author search of the Scopus database (search term: I. Boncz)

8.1.5. Embase

The Embase database is the biomedical bibliographic index of the Elsevier publishing company. At present it contains approximately 28 million records of 8,400 journals.

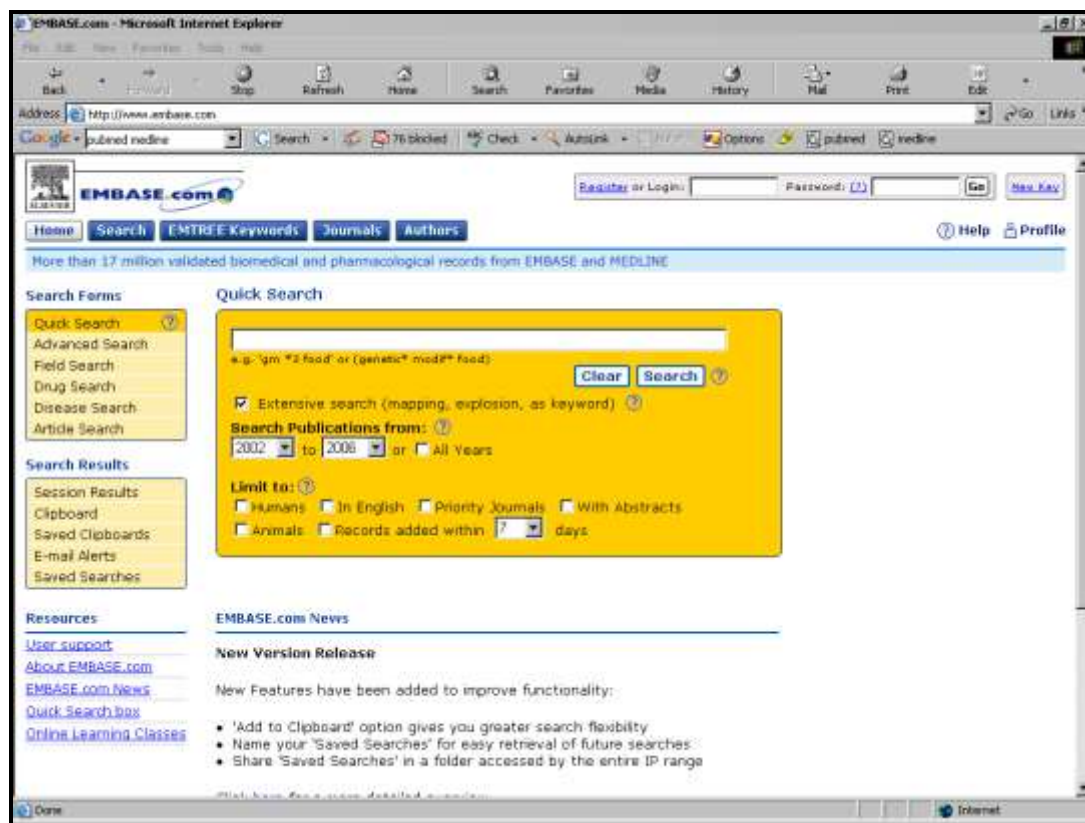


Figure 21

The website of the Embase database (Elsevier)

8.1.6. Econlit

The Econlit database is a special example of economic bibliographic indexes, published by the American Economic Association. Although other databases (e.g. Web of Science) contain plenty of economic journals, the Econlit is the specific database of this subject area. Originally the database was launched in 1969 with 182 publications, the number of which has increased to over 1000 now, with more than 1 million records. Abstracts are available beginning from 1987, and the retrospective enlargement of the database back to 1968 has also begun.

The database contains the following publications:

- journal articles
- books
- collective volumes (e.g. conference proceedings)
- doctoral dissertations
- working papers
- book reviews

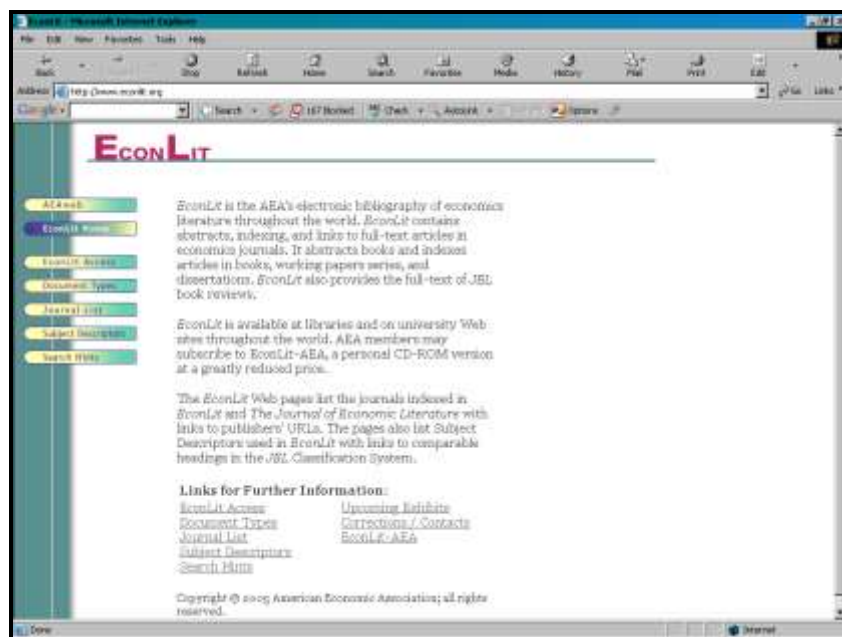


Figure 22
The website of the Econlit database

The Econlit database uses a special system of classification of subject areas, the so-called “JEL Classification System and EconLit Subject Descriptors” coding. The JEL classification is a type of coding developed for the Journal of Economic Literature (JEL), which also serves as a standard in the classification of economic subject areas. The individual main subject areas are illustrated by the table below, highlighting the place of health within that.

Table 11
The main subject areas of the JEL Classification System

- A General Economics and Teaching
- B History of Economic Thought, Methodology, and Heterodox Approaches
- C Mathematical and Quantitative Methods
- D Microeconomics
- E Macroeconomics and Monetary Economics
- F International Economics
- G Financial Economics
- H Public Economics
- I Health, Education, and Welfare**
 - I00 General**

I1 Health

I2 Education and Research Institutions

I3 Welfare and Poverty

J Labor and Demographic Economics

K Law and Economics

L Industrial Organization

M Business Administration and Business Economics • Marketing • Accounting • Personnel
Economics

N Economic History

O Economic Development, Innovation, Technological Change, and Growth

P Economic Systems

Q Agricultural and Natural Resource Economics • Environmental and Ecological Economics

R Urban, Rural, Regional, Real Estate, and Transportation Economics

Y Miscellaneous Categories

Z Other Special Topics

8.1.7. Summary

The main characteristics of the individual bibliographic databases presented above are illustrated by the table below. In the course of their scholarly activities researchers can find useful orientation in these databases concerning earlier publications on a chosen subject. On the other hand, it also provides suggestions where to publish their own research results.

Table 13

Comprehensive table of the bibliographic databases of scholarly literature (last updated in April 2015)

Database	Coverage from	Number of journals	Number of records	Operator / Provider of content	Website
Medline	1946	5,600	22 million	National Institute of Health, National Library of Medicine	http://www.ncbi.nlm.nih.gov/pubmed/
Web of Science	1975	12,000	90 million	Institute for Scientific Information, Thomson Reuters	webofscience.com
CINAHL	1937	5,300	4.5 million	EBSO	https://health.ebsco.com/products/cinahl-complete
Scopus	1996 / 1823	22,800	54 million	Elsevier	www.scopus.com
Econlit	1969 / 1869	1,000	1 million	American Economic Association	www.econlit.org

8.2. HUNGARIAN BIBLIOGRAPHIC DATABASES

8.2.1. Hungarian Medical Bibliography (MOB, Magyar Orvosi Bibliográfia)

As a part of the Hungarian national bibliographic index the National Health Science Library publishes the Hungarian Medical Bibliography (MOB) on CD-ROM, which is also available online as a database, every quarter. The Hungarian Medical Bibliography (MOB) is published as a part of the Hungarian National Bibliographic system in 6 yearly issues from 1957, from 1975 with supplements. Its English version, the Hungarian Medical Bibliography (HMB), was launched in 1961, from 1972 it appears in two issues every year.

The MOB contains articles published in healthcare, medical and other related scientific journals, scholarly books, conference proceedings published on any type of medium as well as the scholarly literature published in foreign languages in Hungary. At present 120 medical journals are processed.

Today the Hungarian Medical Bibliography is also available on the Internet (<http://mob.gyemszi.hu/simplesearch.jsp>). The online interface allows simple and complex searches as well as browsing (by authors' names, subjects, journal titles, keywords)



Figure 23

The search interface of the website of the Hungarian Medical Bibliography (MOB, Magyar Orvosi Bibliográfia)

8.2.2. Electronic Information Provision (EISZ)

The purpose of the Electronic Information Provision (EISZ) national programme is to purchase the electronic sources of information indispensable for higher education and scientific research centrally on the basis of a national licence, which would provide much more information than earlier.

The nationwide database service provided in the framework of the EISZ Basic Programme is an organic part of the research infrastructure, including the bibliographic data and full-text versions of current journals, scholarly papers, scientific publications and the databases necessary for research.

The (centrally supported) databases available in the framework of the EISZ Basic Programme:

- ACM Digital Library
- Akadémiai Journals Collection
- Akadémiai Szótárak
- Cab Abstract
- Econlit
- FSTA
- Grove Art Online
- Grove Music Online
- JSTOR
- MathSciNet
- MLA + LRC
- Nature
- Reaxys
- Science Magazine
- ScienceDirect
- Springerlink
- Web of Science
- Zoological Records

The Electronic Information Provision is accessible via the Internet (<http://www.eisz.hu>).

8.3. SCIENTOMETRIC INDICATORS

The measurement and evaluation of individual and collective performance is a huge challenge in every field of life. In scientific life one faces a similar problem: how to measure the performance of individual researchers and research institutes and the prestige of journals.

The issue of evaluating scientific performance was already raised at the turn of the 1950s and 1960s. It was the initiative of Eugene Garfield, an American linguist.

Garfield established the Institute for Scientific Information (which he sold to the Thomson Corporation in 1992) in 1955. It was the creation of the Science Citation Index (SCI), which organises scientific publications in databases, which created the basis for calculating the indicators of scientific performance.

Today the various scientific bibliographic databases form numerous indicators by which the journals and researchers in the databases can be evaluated and compared according to certain criteria. Two especially important indicators are presented here: the impact factor of journals and scholars' citation impact (with the Hirsch index included).

8.3.1. The impact factor

The impact factor is a measure for the scientific evaluation of journals. It is calculated by dividing the the total number of articles of the two preceding years by the total number of citations received for them in the given year (the following year).

The impact factor lists are published by the American Thomson Reuters on the basis of the Web of Science (WoS) database. The first set of data published was about the year 1975. Originally the impact factor meant the impact of researchers measured by citations.

In Hungary the question is often raised why only scientific and medical journals are measured by the impact factor. It must be stressed here that today impact factor calculations are available for a wide range of social scientific journals. Nevertheless, these enjoy much less interest in Hungary than the areas of medicine, health science or the natural sciences.

8.3.2. science and other related disciplines

Selected examples of the impact factors of journals of health science and other related disciplines

Below some examples of journals with impact factors are presented from a number of selected areas. The subject areas were chosen on the basis of the database of the Thomson Reuters Web of Science (WoS) and the bibliographies of the Science Citation Index Expanded (SCIE) and the Social Sciences Citation Index (SSCI). The focus of the selection was on health science and its related disciplines. Thus, the classic subject areas of medicine are not cited here.

Table 14

Impact factor examples broken down to subject areas: **communication**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	COMMUNICATION RESEARCH	2,186	2.444	0.00435
2	RESEARCH ON LANGUAGE AND SOCIAL INTERACTION	665	2.421	0.00259
3	JOURNAL OF COMMUNICATION	3,061	2.076	0.00608
4	NEW MEDIA & SOCIETY	1,411	2.052	0.00619
5	PUBLIC OPINION QUARTERLY	3,924	2.033	0.00958
6	Journal of Computer-Mediated Communication	2,368	2.019	0.00546
7	PUBLIC UNDERSTANDING OF SCIENCE	1,379	1.932	0.00368
8	HUMAN COMMUNICATION RESEARCH	1,766	1.886	0.00276
9	JOURNAL OF HEALTH COMMUNICATION	1,925	1.869	0.0052
10	POLITICAL COMMUNICATION	1,005	1.825	0.00297
18	MEDIA PSYCHOLOGY	663	1.308	0.00149
19	Information Communication & Society	620	1.283	0.00254
20	HEALTH COMMUNICATION	1,230	1.276	0.00299
35	JOURNAL OF LANGUAGE AND SOCIAL PSYCHOLOGY	560	0.872	0.0012
38	LANGUAGE & COMMUNICATION	563	0.852	0.00086
N=74				

Table 15

Impact factor examples broken down to subject areas: **economics**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	JOURNAL OF ECONOMIC LITERATURE	5,479	6.341	0.02376
2	JOURNAL OF FINANCE	21,843	6.033	0.0524
3	QUARTERLY JOURNAL OF ECONOMICS	16,827	5.966	0.05292
4	JOURNAL OF ECONOMIC PERSPECTIVES	6,688	4.23	0.02197
5	TRANSPORTATION RESEARCH PART B-METHODOLOGICAL	5,300	3.894	0.01133

6	JOURNAL OF FINANCIAL ECONOMICS	15,508	3.769	0.05335
7	JOURNAL OF POLITICAL ECONOMY	16,829	3.617	0.027
8	REVIEW OF FINANCIAL STUDIES	7,614	3.532	0.06368
9	ECONOMETRICA	22,304	3.504	0.04887
10	Journal of the European Economic Association	1,986	3.356	0.01886
12	PHARMACOECONOMICS.	3,397	3.338	0.00615
20	VALUE IN HEALTH	3,929	2.891	0.01452
43	JOURNAL OF HEALTH ECONOMICS	4,321	2.254	0.01466
46	HEALTH ECONOMICS	4,065	2.137	0.01212
52	European Journal of Health Economics	921	1.913	0.00288
N=333				

Among the publications of the subject area of communication (N=74 journals) there are not only journals on general communication but also on health communication. The journals of the subject area of economics deserve extra attention. The Web of Science indexes and calculates the impact factors of several hundreds of economic journal. Without aiming to give an exhaustive list here are some economic subject areas and the number of journals indexed: Business (111), Business, finance (91), Economics (333), Management (173), Operations Research & Management Science (79), Statistics & Probability (119). The table also includes journals on health economics (e.g. Value in Health, European Journal of Health Economics).

Table 16

Impact factor examples broken down into subject areas: **education**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	REVIEW OF EDUCATIONAL RESEARCH	4,139	5	0.0068
2	EDUCATIONAL PSYCHOLOGIST	2,620	4.844	0.00326
3	Journal of Research on Educational Effectiveness	161	3.154	0.00159
4	Educational Research Review	329	3.107	0.00165
5	LEARNING AND INSTRUCTION	2,501	3.079	0.00626
6	JOURNAL OF RESEARCH IN SCIENCE TEACHING	4,200	3.02	0.00804
7	Educational Researcher	2,966	2.963	0.00615
8	SCIENCE EDUCATION	3,245	2.921	0.00623
9	JOURNAL OF THE LEARNING SCIENCES	1,291	2.862	0.00214
10	JOURNAL OF ENGINEERING EDUCATION	1,304	2.717	0.00171
11	ADVANCES IN HEALTH SCIENCES EDUCATION	1,191	2.705	0.00478
19	EARLY CHILDHOOD RESEARCH QUARTERLY	1,958	2.058	0.00439
22	HEALTH EDUCATION RESEARCH	3,582	1.944	0.00631
26	JOURNAL OF SCHOOL HEALTH	2,174	1.659	0.00454

120	HEALTH EDUCATION JOURNAL	706	0.694	0.00145
N=219				

Table 17

Impact factor examples broken down to subject areas: **health policy & services**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	MILBANK QUARTERLY	2,531	5.391	0.0058
2	HEALTH AFFAIRS	10,022	4.321	0.05015
3	Implementation Science	2,388	3.47	0.00986
4	Administration and Policy in Mental Health and Mental Health Services Research	1,141	3.442	0.00382
4	HEALTH POLICY AND PLANNING	2,669	3.442	0.00795
6	PHARMACOECONOMICS.	3,397	3.338	0.00615
7	BMJ Quality & Safety	1,136	3.281	0.00559
8	MEDICAL CARE.	15,916	2.941	0.02494
9	VALUE IN HEALTH	3,929	2.891	0.01452
10	QUALITY OF LIFE RESEARCH	7,814	2.864	0.01317
13	HEALTH SERVICES RESEARCH	4,865	2.491	0.01344
20	Journal of Health Services Research & Policy	1,399	2.087	0.00291
25	European Journal of Health Economics	921	1.913	0.00288
33	HEALTH POLICY.	4,271	1.725	0.00952
38	Health Economics Policy and Law	272	1.593	0.00171
N=69				

Journals on hospitality, leisure, sport and tourism are grouped in a different category. The impact factors of the journals at the top of the list exceed those of, for example, such subject areas as nursing. Another special feature is that a journal even on sport and the interdisciplines of health science is found here too (Journal of Sport and Health Science).

General legal, and more specifically health legal, journals can also be found in the system of the Web of Science under the law category, which indexes 139 journals. At the top of the list one finds the publications of some great American universities but publications with impact factors can also be seen among journals on health law.

Table 18Impact factor examples broken down to subject areas: **hospitality, leisure, sport & tourism**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	International Review of Sport and Exercise Psychology	184	3.353	0.00088
2	ANNALS OF TOURISM RESEARCH	4,480	2.795	0.00326
3	JOURNAL OF SPORT & EXERCISE PSYCHOLOGY	2,745	2.593	0.00348
4	Journal of Sustainable Tourism	1,401	2.392	0.0025
5	TOURISM MANAGEMENT	5,352	2.377	0.0075
6	Journal of Travel Research	2,577	1.884	0.00219
7	International Journal of Hospitality Management	1,899	1.837	0.00341
8	PSYCHOLOGY OF SPORT AND EXERCISE	1,755	1.768	0.00431
9	International Journal of Contemporary Hospitality Management	1,037	1.623	0.00103
10	SPORT EDUCATION AND SOCIETY	610	1.333	0.00118
13	Journal of Sport and Health Science	50	1.227	0.00017
15	SOCIOLOGY OF SPORT JOURNAL	664	1.125	0.00115
20	JOURNAL OF SPORT & SOCIAL ISSUES	505	1.049	0.00114
25	JOURNAL OF SPORT MANAGEMENT	504	0.727	0.0008
32	Journal of Sports Economics	421	0.544	0.00085
N=39				

Table 19Impact factor examples broken down to subject areas: **law**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	HARVARD LAW REVIEW	4,274	6.567	0.00458
2	YALE LAW JOURNAL	3,554	3.273	0.0039
3	STANFORD LAW REVIEW	2,289	2.887	0.00336
4	MICHIGAN LAW REVIEW	1,780	2.712	0.00259
5	COLUMBIA LAW REVIEW	2,671	2.398	0.00334
6	GEORGETOWN LAW JOURNAL	1,203	2.278	0.00307
7	UNIVERSITY OF PENNSYLVANIA LAW REVIEW	1,721	2.256	0.00327
8	UCLA LAW REVIEW	1,010	2.246	0.00238
9	CALIFORNIA LAW REVIEW	1,582	2.23	0.0033
10	LAW AND HUMAN BEHAVIOR	2,302	2.153	0.00399
48	JOURNAL OF LAW MEDICINE & ETHICS	1,161	0.939	0.00431
61	MEDICINE SCIENCE AND THE LAW	525	0.758	0.00059
64	Medical Law Review	156	0.729	0.00058
117	Asian Journal of WTO & International Health Law and Policy	23	0.194	0.00007
126	ISSUES IN LAW & MEDICINE	28	0.143	0.00005
N=139				

Currently (in 2015) within the subject area of nursing 107, and in nutrition and dietetics 79 journals with an impact factor can be found. That means that at an international level nursing, nutrition and dietetics have managed to gain a serious position, which makes the scientific achievements produced in these areas comparable with those of the classic areas of medicine. For the development of these disciplines in Hungary it would be desirable if more and more Hungarian authors could publish their results in these international journals.

Table 20

Impact factor examples broken down to subject areas: **nursing**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	ONCOLOGY NURSING FORUM	2,751	2.83	0.00414
2	Worldviews on Evidence-Based Nursing	468	2.318	0.00117
3	INTERNATIONAL JOURNAL OF NURSING STUDIES	4,214	2.248	0.01041
4	BIRTH-ISSUES IN PERINATAL CARE	1,744	2.048	0.00292
5	International Journal of Mental Health Nursing	745	2.009	0.00157
6	JOURNAL OF HUMAN LACTATION	1,049	1.977	0.00172
7	Journal of Pediatric Health Care	651	1.97	0.00138
8	CANCER NURSING	2,543	1.931	0.00395
9	NURSING OUTLOOK	821	1.831	0.00189
10	European Journal of Cardiovascular Nursing	714	1.828	0.00175
12	Journal of Cardiovascular Nursing	1,172	1.809	0.00296
13	European Journal of Oncology Nursing	1,057	1.794	0.00271
17	MIDWIFERY	1,672	1.707	0.00325
19	JOURNAL OF ADVANCED NURSING	11,383	1.685	0.01414
24	NURSE EDUCATION TODAY	2,503	1.456	0.00351
N=107				

Table 21

Impact factor examples broken down to subject areas: **(nutrition & dietetics)**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	PROGRESS IN LIPID RESEARCH	4,382	12.963	0.00883
2	Annual Review of Nutrition	4,846	10.459	0.00579
3	AMERICAN JOURNAL OF CLINICAL NUTRITION	52,237	6.918	0.0829
4	CRITICAL REVIEWS IN FOOD SCIENCE AND NUTRITION	5,097	5.548	0.008
5	NUTRITION REVIEWS	5,560	5.541	0.01181
6	INTERNATIONAL JOURNAL OF OBESITY	19,384	5.386	0.03633

7	PROCEEDINGS OF THE NUTRITION SOCIETY	4,464	4.937	0.00692
8	Advances in Nutrition	783	4.891	0.00399
9	JOURNAL OF NUTRITIONAL BIOCHEMISTRY	6,776	4.592	0.01349
10	Obesity	12,815	4.389	0.04996
14	JOURNAL OF THE AMERICAN DIETETIC ASSOCIATION	9,551	3.922	0.01618
40	Journal of the Academy of Nutrition and Dietetics	538	2.444	0.00181
48	JOURNAL OF HUMAN NUTRITION AND DIETETICS	1,434	2.074	0.00333
69	Nutrition & Dietetics	363	0.659	0.00093
72	ACTA ALIMENTARIA	306	0.427	0.00042
N=79				

Public, environmental and occupational health and sport sciences journals have separate WoS categories. Both subject areas can boast of journals with outstanding impact factors. At the top of the list there are journals with impact factors of more than 9 but even the journals ranked around 20 have impact factors over 2.

Table 22

Impact factor examples broken down to subject areas: **(public, environmental and occupational health**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	INTERNATIONAL JOURNAL OF EPIDEMIOLOGY	15,985	9.197	0.03865
2	EPIDEMIOLOGIC REVIEWS	2,953	7.333	0.0051
3	ENVIRONMENTAL HEALTH PERSPECTIVES	31,363	7.029	0.05479
4	Annual Review of Public Health	3,779	6.627	0.00693
5	EPIDEMIOLOGY	9,837	6.178	0.02584
6	JOURNAL OF CLINICAL EPIDEMIOLOGY	17,222	5.478	0.03072
7	TOBACCO CONTROL	4,821	5.15	0.01147
8	EUROPEAN JOURNAL OF EPIDEMIOLOGY	4,678	5.147	0.01108
9	JOURNAL OF TOXICOLOGY AND ENVIRONMENTAL HEALTH-PART B-CRITICAL REVIEWS	1,247	5.146	0.00306
10	BULLETIN OF THE WORLD HEALTH ORGANIZATION	11,901	5.112	0.02221
12	CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION	20,408	4.324	0.0506
14	AMERICAN JOURNAL OF PUBLIC HEALTH	27,247	4.229	0.05061
27	PREVENTIVE MEDICINE	10,665	2.932	0.0211
36	JOURNAL OF MEDICAL SCREENING	1,075	2.722	0.00285
49	EUROPEAN JOURNAL OF PUBLIC HEALTH	3,591	2.459	0.00999
N=162				

Table 23Impact factor examples broken down to subject areas: **sport sciences**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	EXERCISE IMMUNOLOGY REVIEW	513	9.929	0.00117
2	SPORTS MEDICINE	7,817	5.32	0.01051
3	EXERCISE AND SPORT SCIENCES REVIEWS	2,200	4.818	0.00403
4	AMERICAN JOURNAL OF SPORTS MEDICINE	19,452	4.699	0.0364
5	MEDICINE AND SCIENCE IN SPORTS AND EXERCISE	26,935	4.459	0.03914
6	BRITISH JOURNAL OF SPORTS MEDICINE	9,746	4.171	0.02058
7	JOURNAL OF APPLIED PHYSIOLOGY	42,489	3.434	0.04704
8	SCANDINAVIAN JOURNAL OF MEDICINE & SCIENCE IN SPORTS	4,597	3.174	0.01284
9	JOURNAL OF SCIENCE AND MEDICINE IN SPORT	2,967	3.079	0.00895
10	KNEE SURGERY SPORTS TRAUMATOLOGY ARTHROSCOPY	6,620	2.837	0.01883
16	INTERNATIONAL JOURNAL OF SPORTS MEDICINE	5,915	2.374	0.00824
21	JOURNAL OF SPORTS SCIENCES	6,288	2.095	0.01143
49	Journal of Sport and Health Science	50	1.227	0.00017
59	International Journal of Performance Analysis in Sport	399	0.845	0.00057
77	ACSMS HEALTH & FITNESS JOURNAL	56	0.268	0.00011
N=81				

In the interdisciplinary aspects of health sciences regarding social work and sociology one can also find prestigious journals recognized at an international level too. Many of them specifically deal with the healthcare aspects of social work or sociology.

Table 24Impact factor examples broken down to subject areas: **social work**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	Trauma Violence & Abuse	887	2.939	0.00239
2	CHILD MALTREATMENT	1,374	2.706	0.00299
3	CHILD ABUSE & NEGLECT	5,989	2.135	0.00765
4	AMERICAN JOURNAL OF COMMUNITY PSYCHOLOGY	3,499	1.968	0.00532
5	JOURNAL OF SOCIAL POLICY	826	1.632	0.00209
6	AMERICAN JOURNAL OF ORTHOPSYCHIATRY	2,577	1.504	0.00353
7	BRITISH JOURNAL OF SOCIAL WORK	1,501	1.162	0.0038
8	HEALTH & SOCIAL CARE IN THE COMMUNITY	1,241	1.151	0.00272
9	SOCIAL POLICY & ADMINISTRATION	633	1.143	0.00178
10	Revista de Cercetare si Interventie Sociala	152	1.141	0.00032
14	HEALTH & SOCIAL WORK	615	0.895	0.0008
15	SOCIAL WORK	1,181	0.877	0.00124
19	Child & Family Social Work	555	0.824	0.00106
24	SOCIAL WORK IN HEALTH CARE	634	0.66	0.00099
35	Social Work in Public Health	92	0.333	0.00048
N=40				

Table 25Impact factor examples broken down to subject areas: **sociology**

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	AMERICAN SOCIOLOGICAL REVIEW	12,515	4.266	0.01447
2	AMERICAN JOURNAL OF SOCIOLOGY	11,681	4.045	0.01192
3	Annual Review of Sociology	6,083	3.63	0.01024
4	ANNALS OF TOURISM RESEARCH	4,480	2.795	0.00326
5	SOCIOLOGICAL THEORY	1,193	2.586	0.00291
6	POPULATION AND DEVELOPMENT REVIEW	2,349	2.306	0.00371
7	SOCIOLOGICAL METHODS & RESEARCH	2,178	2.292	0.00337
8	SOCIOLOGY OF EDUCATION	1,710	2.27	0.00268
9	SOCIAL NETWORKS	2,683	2.138	0.00601
10	SOCIOLOGY OF HEALTH & ILLNESS	2,683	2.014	0.0057
23	SOCIAL INDICATORS RESEARCH	3,767	1.452	0.00718
52	JOURNAL OF SPORT & SOCIAL ISSUES	505	1.049	0.00114
98	SOCIOLOGICKY CASOPIS-CZECH SOCIOLOGICAL REVIEW	160	0.563	0.00031
106	Health Sociology Review	234	0.456	0.00074
134	Polish Sociological Review	38	0.034	0.00007
N=135				

8.3.3. Measuring the citation impact: the Hirsch index

The impact of scientific publications and, thus, that of the authors' work is often characterized by the number of citations received for them. Citations are classified as independent and dependent citations. One talks of independent citations if none of the citing and the cited authors is identical. A citation is regarded as dependent or self-cited if at least one of the citing and the cited authors is identical. That means that if a publication by 8 authors is cited in another publication by 9 authors, the criterion of independence is fulfilled only if none of the 17 authors of the two publications is identical.

It was in 2005 upon the initiative of the American physicist Jorge Hirsch that an index measuring the citations received, later named Hirsch index after him, was first used to measure the scientific performance of individuals. In calculating the Hirsch index the publications are ordered with the one receiving the most citations in the first place and then the others in an order of decreasing number of citations. The h-index is the ordinal number of the position whose citations are at least as many as those of the number of the position. Thus, by definition, an author's index is h if he/she has exactly h articles that have received at least h citations (i.e. his/her papers have received fewer than that).

An undoubted advantage of the Hirsch index is that it can be calculated on the basis of numerous databases (e.g. Web of Science, Scopus, MTMT, google scholar, etc.).

The table below illustrates how the Hirsch index is calculated on the basis of the Scopus database (author: I. Boncz). In the table 15 of the author's publications receiving the most citations were ordered with the one receiving the most in first place and the one with the fewest in 15th place. As you can see the publications in the first 10 places have received a higher number of citations than the number of their positions. In the case of the publication in 11th place the number of citations is the same as that of the position. So, the Hirsch index is 11.

Table 26

Example for a Hirsch-index calculation (Scopus database, I. Boncz author; Hirsch-index = 11)

Documents	Citations	Title
1	34	Epidemiology of osteoporosis related fractures in Hungary from the nationwide health insurance database, 1999-2003
2	32	Financing of health care services in Hungary
3	22	Financial deficits in the health services of the UK and Hungary
4	21	Issues for countries considering introducing the "fourth hurdle": The case of Hungary
5	20	The organisation and results of first screening round of the Hungarian nationwide organised breast cancer screening programme
6	16	Effect of surgical delay on early mortality in patients with femoral neck fracture
7	16	Cervical screening in Hungary: Why does the "English model" work but the "Hungarian model" does not?
8	14	Prevention of cervical cancer in low-resource settings
9	13	The effect of an organized, nationwide breast cancer screening programme on non-organized mammography activities
10	12	Health economics analysis of colorectal screening
11	11	The disease burden of colorectal cancer in Hungary
12	11	Organized, nationwide cervical cancer screening programme in Hungary
13	10	Capacity building for HTA implementation in middle-income countries: The case of Hungary
14	10	History of health technology assessment in Hungary
15	10	Development of health economics in Hungary

8.3.4. Database of Hungarian Scholarly Works (Magyar Tudományos Művek Tára, MTMT)

The goal of establishing and operating the Database of Hungarian Scholarly Works (MTMT) is to have a national bibliographic database in Hungary that can serve a great number of purposes. The Hungarian Academy of Sciences, the Hungarian Accreditation Committee, the Hungarian Rectors' Conference, the Hungarian Scientific Research Fund and the Hungarian Doctoral Council began the negotiations in the second half 2008.

In the MTMT system researchers' scientific publications are recorded including publications which are already listed in various international bibliographic databases and also those that are not. Thus, the MTMT database provides a comprehensive picture of individual researcher's, teams' of researchers and entire institution's scholarly achievements.

The use of the MTMT has become widespread in the academic-scholarly sector within institutions as well as at a national level:

- PhD dissertations
- Habilitation
- Application for the post of a university full professor
- Applications for the posts of heads of departments, institute directors
- MTA Bolyai János Research Grant
- Doctor of the Hungarian Academy of Sciences applications
- Hungarian Academy of Sciences *Lendület* programme
- Hungarian Academy of Sciences research team applications
- Hungarian Accreditation Committee accreditations (programmes, institutional, doctoral schools)
- research grant applications
- budget resource allocation (e.g. funds for research universities)

The scholarly achievements recorded in the Database of Hungarian Scholarly Works are presented in the standard tabular form shown below. In this all the most important summarized data of the publications and their citations can be found.

Table 27

Standard comprehensive table of publications and citations of the MTMT

Comprehensive table of MTMT publications and citations				
Data of I. Boncz adatai (29/05/2013)				
Publication types	Number		Citations	
Full-text scientific publications	Total	Detailed	Independent	Total
Scholarly journal article	132	---	---	---
in international journal	---	24	157	209
in a foreign language in a journal published in Hungary	---	2	0	0
in Hungarian in a journal published in Hungary	---	106	130	179
II. Books	0	---	---	---
a) Book, as an author	0	---	---	---
in a foreign language	---	0	0	0
in Hungarian	---	0	0	0
b) Book, as an editor	0	---	---	---
in a foreign language	---	0	---	---
in Hungarian	---	0	---	---
III. Book chapter	12	---	---	---
in a foreign language	---	2	0	0
in Hungarian	---	10	1	3
IV. Conference publication in a journal or in conference proceedings	3	---	---	---
In a foreign language	---	0	0	0
In Hungarian	---	3	1	1
Total of scholarly publications (I-IV.)	147	---	289	392
Further scholarly works	---	79	72	114
Aggregate impact factor	71.9	---	---	---
Number of citations	---	---	378	550
Hirsch index	10	---	---	---
Educational works				
Textbook for higher education	3	---	---	---
In a foreign language	---	0	0	0
In Hungarian	---	1	0	0
Chapter of textbook for higher education in a foreign language	---	0	0	0
Chapter of textbook for higher education in Hungarian	---	2	3	3
Further educational works	0	---	0	0
Patents	0	---	0	0
Work of art	0	---	0	0

Popular scientific works				
Books	0	---	0	0
Further works	0	---	0	0
Works of public interest and uncategorized works	0	---	0	0
Abstract	222	---	17	44
Other authorship	0	---	0	0
Citations in dissertations, in other types of works	0	---	31	39

8.4. DISCUSSION

The publication of scientific works and the availability of the publications have an enormous role in the development of the careers of individual researchers and the enhancement of the reputation of academic-research institutions.

The discipline of health science is present in the scientific scene in Hungary with an ever-increasing research portfolio and an ever-growing number of publications. The strengthening of the publication activity of the various subject areas is really welcome:

- nutrition and dietetics
- nursing
- public health sport science
- physiotherapy
- health economics
- social sciences

The development of a new area, such as that of the health sciences, has several elements and stages, in which the strengthening of the scientific potentials plays an important role. A profession can only become successful if it successfully integrates into the evaluation systems of international scholarly life.

9. GRAPHICAL REPRESENTATION OF DATA (I. ÁGOSTON, I. BONCZ)

9.1. INTRODUCTION

Representing data in a graphical form looks back on a history of almost two centuries; it is of the same age as modern statistics. An important element of statistical analyses is the graphical representation of the results produced by statistical work, which is equally important to both the person(s) carrying out the statistical work and those reading the publication. By graphical diagrams statisticians can present and publish their results in an easily comprehensible form, since several hundreds or even thousands of data can only be presented in a certain way. Furthermore, so-called working charts help statisticians in certain phases of their work; they can only make decisions on how to proceed with their investigation with the help of well-designed charts. For the readers of publications it is important to become familiar with the rules of chart construction as that is the only way to be able to interpret the contents of a chart appropriately. Nowadays the significance of graphical representation is growing even more, on the one hand, due to the dramatic development of computers, tablets and smart phones and the spread of user-friendly statistical software and, on the other hand, because of people's increased information need and for the easier interpretation of the information obtained. Graphical presentation has a relatively large literature, of which the following have been taken into account here. In order to demonstrate the different types of diagrams in this chapter, the various visualization techniques are presented using charts from existing publications, mainly those of the Hungarian Central Statistical Office and our own works, of course with the strict use of proper referencing.

9.2. THE RULES OF DESIGNING TABLES

Before introducing the rules and types of graphical representation it is necessary to recall the rules of designing tables in a few sentences, so that the data serving as the basis of graphical representation will be well arranged to help both the work of the statistician as well as the comprehension of the reader of the statistical publication.

Statistical tables are created by joining individual statistical rows, which is suitable for presenting relationships in a clear, well-arranged form. Simple tables consist of two statistical rows and do not contain grouping. If a statistical table contains groups according to one

criterion, it is called a grouping table, in the case of tables containing groups according to several criteria one talks about combination tables.

Of the rules of table design it is necessary to emphasize that every table must be numbered and bear a title that clearly indicates what the table is about and to what period and geographical location it refers to. Every column and row must be marked by a clear name and the measure used, which in the case of a homogenous table may even be given in the title of the table, must also be given exactly. The totals and in certain cases also the subtotals must be indicated in the table. If some cells contain no data, the reason for that must be clearly indicated according to the following:

- if it cannot be indicated by the measure used in the table, it is shown by a zero (0)
- if it does not occur, it is indicated by a hyphen (-)
- if there is no data available, it is indicated by a dot (.)

9.3. THE PRINCIPLES OF GRAPHICAL REPRESENTATION

The principles of graphical representation are summarized differently in the literature. Here the categories used by Hunyadi [1] are presented.

1. **Clarity** A chart must be simple and well-arranged. This principle must be applied also to the shape of the chart as well as the colours or backgrounds used. When preparing coloured charts it must be born in mind that the colours used must remain easily interpretable also in black and white print and the colour of the background must not interfere with the visibility of the figures.
2. **Goal-orientation** A graphical figure should represent one phenomenon if possible. So-called “double-barrelled” figures which represent two phenomena in a co-ordinate system are only worth using if the phenomena belong together and one wants to present their relationship emphatically. In general, however, “double-barrelled” figures are to be avoided, especially if due to double scaling figures that are unclear and hard to comprehend are produced.
3. **Simplicity** Thanks to the spread of modern statistical software three-dimensional statistical figures are becoming more and more common. Although they are pleasing to the eye, the third dimension has no comprehensible function; in certain cases it may even hinder the proper overview of the phenomenon.

4. **Reconstructability** Information on the sources of the data and the methodology must be included in the figure or in the text directly connected to it. The minimum requirements of statistical figures and the general rules of figure design are presented in the next subchapter.
5. **Optical neutrality** Statistical figures must be sized and scaled so that they can be in the greatest harmony possible with the content of the analysis. Breaking the axes should be avoided and if it is absolutely indispensable, must be clearly indicated.
6. **Homogeneity** One type of figure should be used for one type of phenomena if possible, in order to help users with the interpretation of the information provided. In the chapter titled 'Applied figure types' we try to provide help with the selection of suitable figure types.

9.4. THE GENERAL RULES OF DESIGNING FIGURES

In preparing statistical figures the following rules, whose application is illustrated by the diagram below, must also be kept in addition to the principles above.

1. **The title of the figure.** The title of a figure must always be short and to the point and it must contain the object, location, time and duration of the given phenomenon. Figures always have to be numbered by Arabic numerals.
2. Figures must always have an appropriate **legend**. The legend must cover the phenomena examined and they must be properly separated from one another. In some cases it may be reasonable to use abbreviations even in the legend, especially if an extensive legend could divert attention from the important content elements of the figure. In the case of examining more than one aspect they must be clearly separated, either by different colours or by using different line types.
3. **The axes.** In statistical figures the horizontal X axis is usually numbered from left to right, while the vertical Y axis is numbered from the bottom to the top. Zero is usually located at the intersection of the two axes. In the figure the end points of the axes have to be indicated too, and the measure used must also be indicated.
4. **Scale** The correct determination of the scale applied on the axes of a statistical table is of paramount importance for the design of the figure as in a large scale small variations cannot be properly presented, while in the case of a small scale the size of the figure might be too large. With the exception of working tables the use of logarithmic scales

should be avoided as they are difficult to understand to lay users: Nevertheless the application of logarithmic scales may be necessary when representing extreme variations.

9.5. TYPES OF FIGURES USED

In representing statistical work numerous types of figures, all of which have their own specific areas of application, may be used.

1. Charts
 - a. Line chart
 - i. Point chart
 - ii. Simple line chart
 - b. Bar chart
 - i. Simple bar chart
 - ii. Horizontal bar chart
 - iii. Stacked bar chart
 - iv. Stick diagram
 - v. Histogram
 - vi. Frequency polygon
 - c. 3D diagram (3D histogram)
 - d. Pie chart
2. Cartogram, (statistical map) cartodiagram, dot distribution map
3. Pictogram
4. Complex statistical charts
 - a. Radar chart
 - b. Stem-and-leaf display
 - c. Box plot
 - d. Cluster

9.5.1. Line chart

This is one of the most common types of charts, which is usually used for representing data in a fixed order, for example chronological series but it can also be used for representing fixed order quantitative series. In the case of displaying chronological series the temporal criterion is shown along the horizontal axis of the coordinate system with the progression of time from

left to right. The scale measuring the change of the phenomenon is located on the vertical axis and in the intersections of the two values the dots represent the given statuses.

When the points shown in a coordinate system are not connected, a **point chart** is created. It is suitable to express the separateness of individual phenomena better. In certain cases point charts may be supplemented with trend lines. Thus, functioning as a working chart, it can help statistical analysis and reaching right conclusions, while, on the other hand, it can make it easier for the readers of the completed statistical work to interpret conclusions by visually representing for them the trends that provided a basis for conclusions.

4. ábra. A teljes termékenységi arányszám és a nők átlagos életkorának százalékos változása az első és a második elveszületési sorrend szerint Magyarországon, 1970–2010

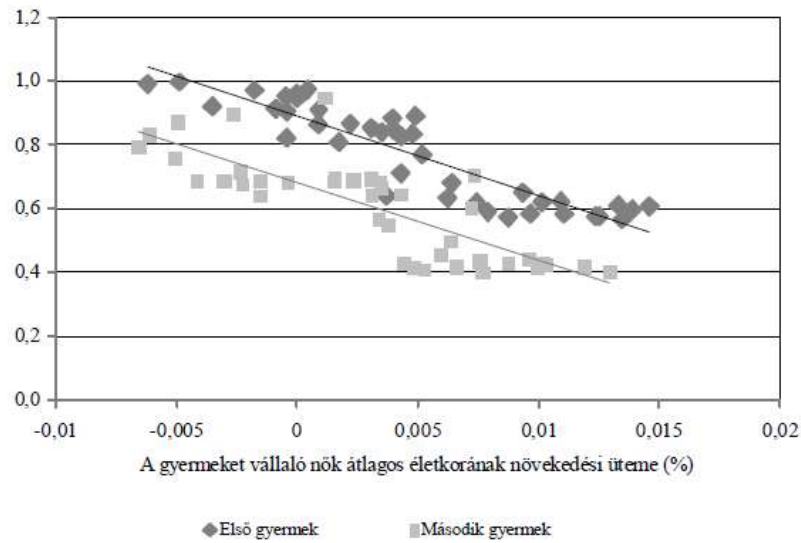


Figure 13: Example illustrating the structure of a point chart

In some cases detailed legends are indispensable for interpreting point charts, which is shown in the figure below. Point charts may serve as starting points for preparing other more complex statistical tables and techniques, such as cluster analysis.

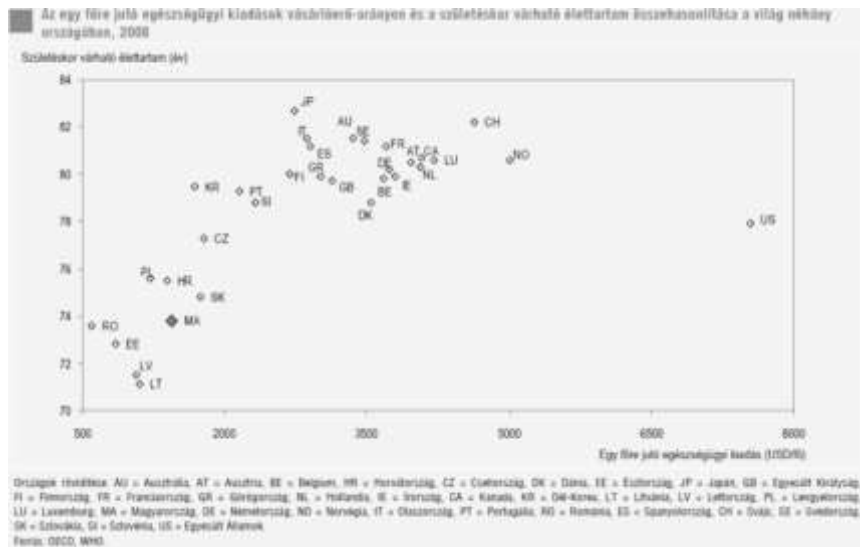


Figure 14: Example illustrating the structure of a point chart with a detailed legend

In line charts the points obtained are connected by a line, which is suitable for representing the tendencies in the chronological series and to show that there is a continuous relationship between the individual elements of the phenomenon. The points indicating the values may be shown in the chart but if the tendency of the phenomenon is the primary subject of the

investigation, they may be omitted. In certain cases different line types can help differentiate between the individual data series.

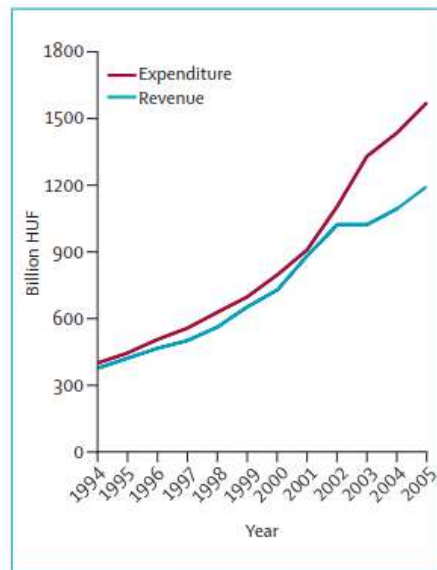


Figure: Expenditure and revenue of Hungarian OEP between 1994 and 2005

Figure 15: Example illustrating the structure of a line chart

In healthcare the most obvious examples of using line charts are fever, pulse or ECG charts. In the example below the latter is shown.



Figure 16: An example of using line charts in healthcare (ECG)

In the case of two or more chronological series line charts may be suitable for illustrating the relationships between them. A typical example for this is the representation of natural increase and decrease obtained as the sum of live births and deaths often used in

epidemiology or the representation of surplus and/or deficit defined as a sum of the revenues and expenditures in health economics.

Figure 17: Example of the use of a line chart showing the natural increase and decrease of the population

In the case of line charts it may be necessary to display the separate and cumulative values of the different sets of individual data together at the same time as well as in progress. In such a case it is especially important to apply suitable colours and a detailed legend.

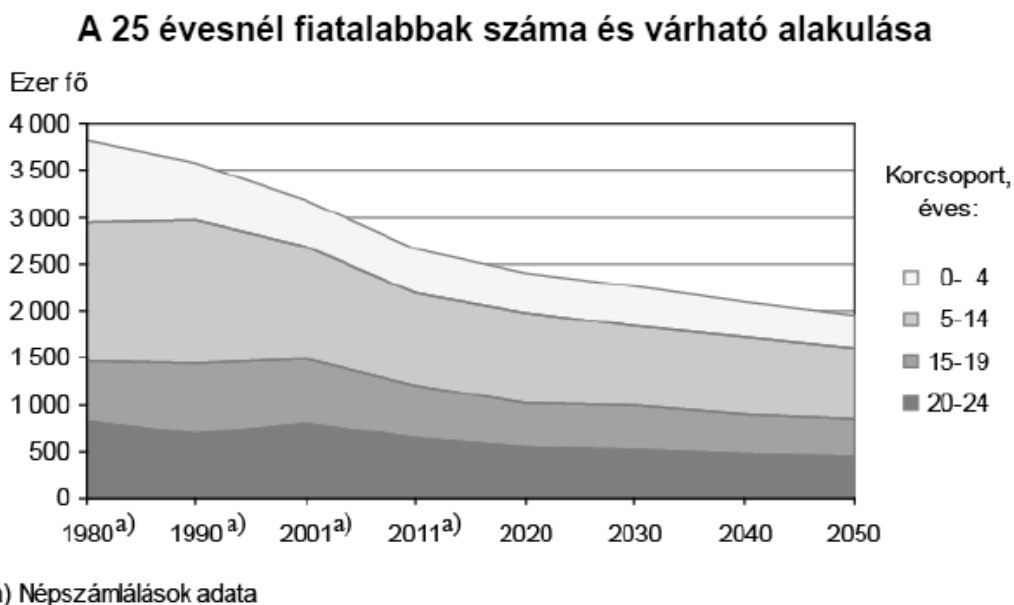


Figure 18: Sample chart representing the structure of a line chart suitable for representing cumulative values

9.5.2. Bar chart

Bar charts are mainly suitable for the analysis of chronological series where the periods of time are shown along the horizontal axis, above which the various phenomena are represented by bars of equal widths but different heights. It is an interesting phenomenon that in spite of the fact that the observation periods follow one another without interruption, there are spaces between the bars representing the individual phenomena. The reason for that is that due to the principle of homogeneity one type of chart is used for one type of phenomenon, and a diagram with bars without spaces between them would be easily mistaken for histograms,

which play a specific role in statistics and are presented later in this book. Bar charts can in certain cases even be replaced by line charts provided the variable values of the phenomena belong to the middle of the time periods.

3. ábra. Az aktiv fekvőbeteg-ellátásban részesülők átlagos életkora

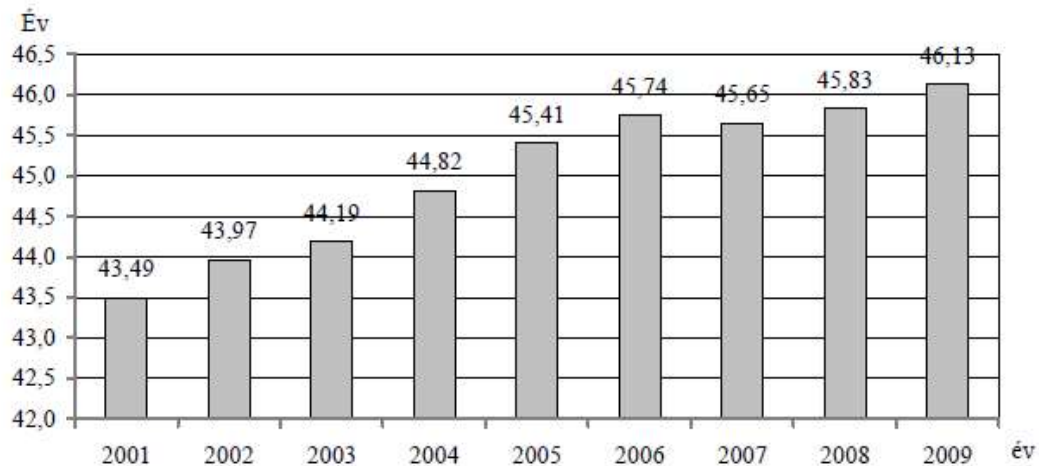


Figure 19: Example illustrating the structure of a simple bar chart

In horizontal bar charts the bars are horizontal. They are equally suitable to represent temporal, areal, quantitative and qualitative series too. In the case of a high number of versions of qualitative characteristics horizontal bar charts may be used to replace circular charts, which best represent neutrality.

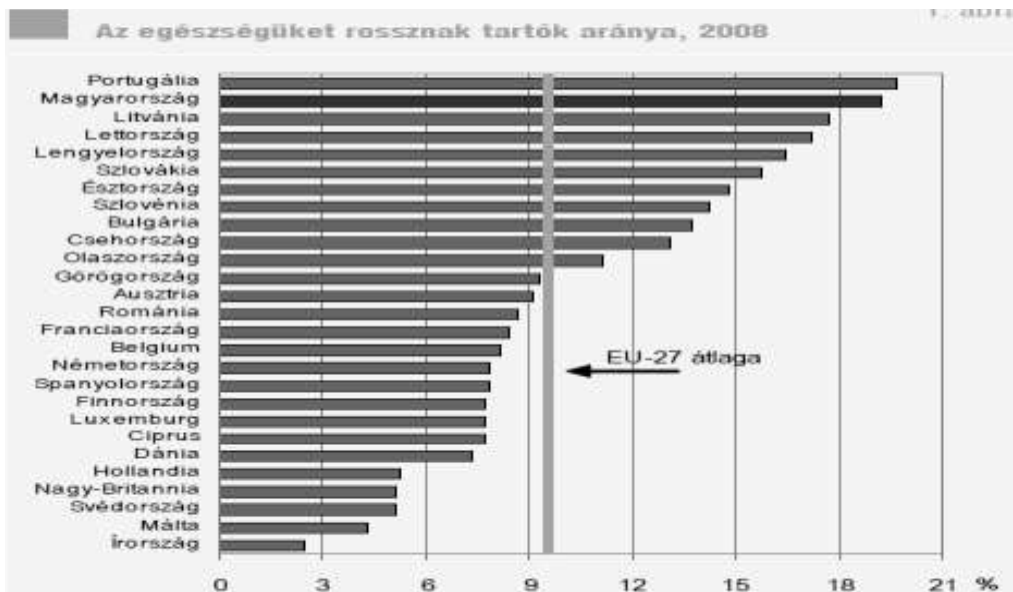


Figure 20: Example illustrating the structure of a horizontal bar chart

Its best-known form used in healthcare is the population pyramid from demographic researches, showing the age distribution of the population by sexes.

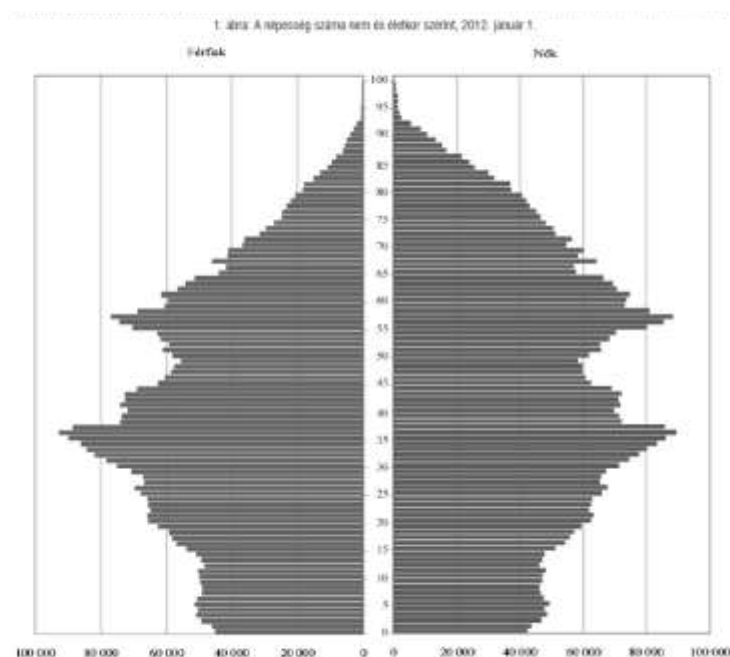


Figure 21: Example of the application of a horizontal bar chart in demographic research (population pyramid)

Stacked bar charts are suitable to display the individual and cumulative values of the different subgroups of individual data series together. For the proper overview of a statistical figure the

use of an appropriate legend is indispensable as well as the choice of the right colours as described by the principles of diagram design.

A 20–29 évesek megoszlása legmagasabb iskolai végzettségük szerint, 2000–2010

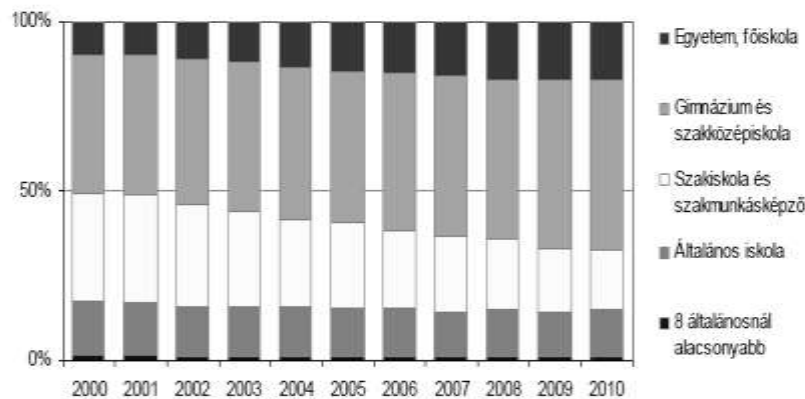


Figure 22: The structure of a stacked bar chart

Stick diagrams can be used if the criterion for grouping is discreet and has relatively few versions. The points representing the values are not connected in this case due to stressing the discreet nature of the criteria. It may be said, however, that although this form of representation would be more suitable professionally for presenting the phenomenon examined, bar charts are mostly used instead. Thus, no further presentation of this type of chart is provided here.

Histograms are used to display the distribution of social phenomena according to qualitative criteria if the grouping criteria are continuous, such as income or age. Histograms are bar charts where there are no spaces between the bars, and the dividing lines between the bars are often not indicated either. In the case of histograms it is important to choose appropriate and equal sized class intervals, and if this is not possible, the data have to be converted to equal class intervals. Histograms are suitable to demonstrate absolute distribution ratios as well as ratios representing relative frequency.

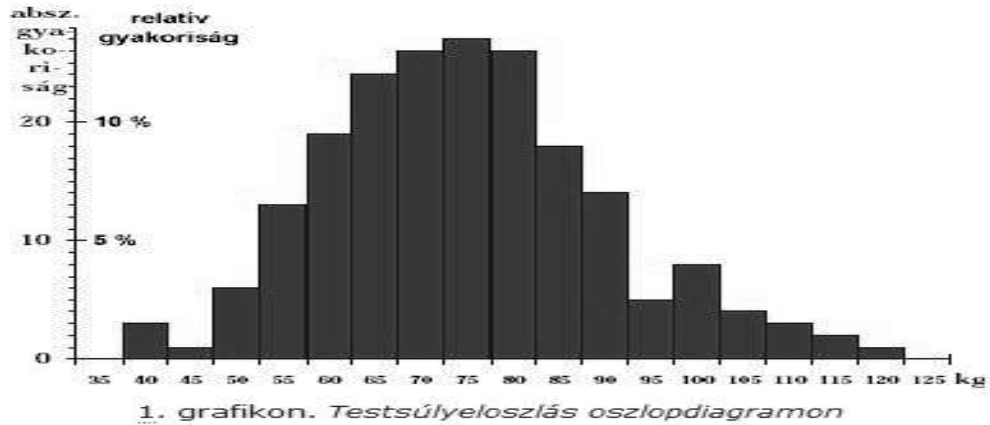
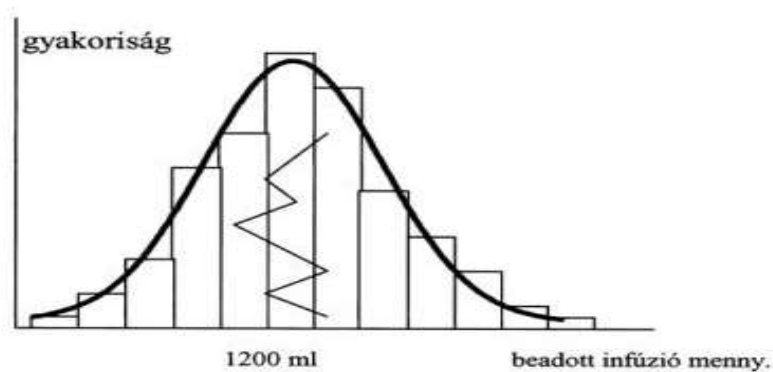


Figure 23: The structure of a histogram

Frequency polygons are created by connecting the centres of the bars of a histogram with straight lines, which is none other than distribution density used in probability calculations, the best-known of which is Gaussian distribution.



8. ábra – A beadott infúziómennyiség gyakorisági hisztogramja

Figure 24: Example illustrating the structure of a frequency polygon

9.5.3. Pie chart

A pie chart is a statistical graphic primarily used in the case of distributions according to qualitative criteria. It is very spectacular, so it is often used for presenting statistical data that are of interest to a wide range of people. The pie chart is capable of representing the individual criteria neutrally as a circle does not imply any order, which other methods of representation based on a conventional coordinate system are not suitable for. During design it must be born in mind that $1\% = 3.60^\circ$, and one starts from the right horizontal radius and

proceeds counterclockwise. The use of appropriate legends is also important in this visual technique. Pie charts may also be suitable for representing two criteria simultaneously but in such a case two pie chart charts must be created paying attention to the requirement of areal proportions.

A nappali tagozatos hallgatók megoszlása képzési szint szerint*



Figure 25: Example illustrating the structure of a pie chart

In certain cases it may be necessary to represent the inner contents and proportions of the individual slices. That can be achieved by the joint use of a pie chart and a bar chart, in which case sufficiently informative legends are especially important as well as the clear explanation of the relationships between the different diagram types, which is illustrated by the figure below.

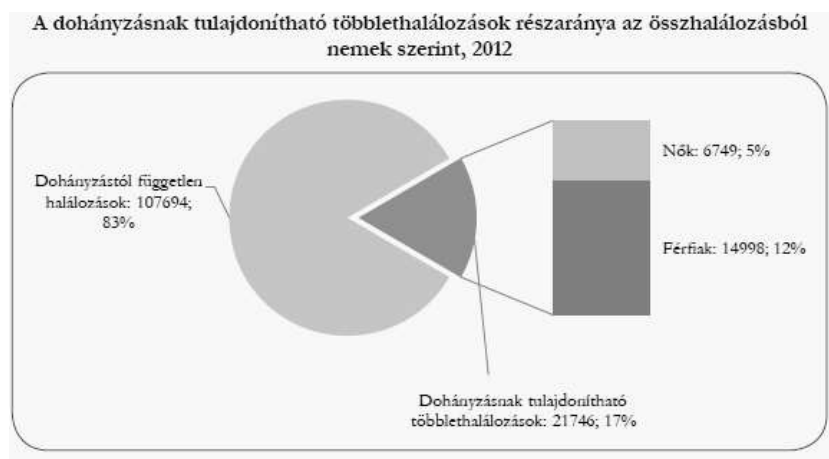


Figure 26: The joint use of a pie chart and a bar chart

9.5.4. 3D diagram

In 3D diagrams the populations are characterized by the volumes of geometrical bodies, but it is extremely difficult to represent the exact proportions. This problem is usually solved by making the 3D diagram retraceable to a one-dimensional diagram. That is why geometrical bodies with identical areas but differing heights are used. The most common type is when bar charts are represented not by blocks but pyramids, cones or cylinders. The application of 3D diagrams is advisable when the differences between the data are significant and can be represented in space. Nevertheless, most of the time users just want to create more spectacular diagrams, which are made possible by modern computer software. However, considering the principle of reason, 3D statistical diagrams are only worth making if the third dimension has an important and comprehensible function. For example, such a purpose can be the case of two-dimensional distributions, where the versions of the two criteria are displayed along the axes bordering the horizontal plane and the combined frequencies are shown in the third dimension. That is called a 3D histogram.

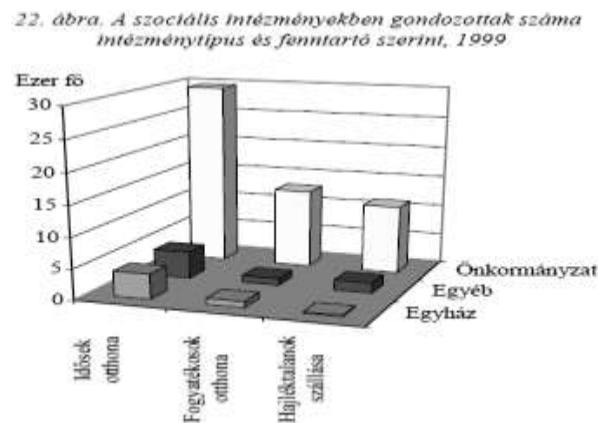


Figure 27: Example illustrating the structure of a 3D diagram

9.5.5. Cartogram, cartodiagram, dot distribution map

Cartograms, also called statistical maps, are a type of graphical representation for displaying the areal distributions of some social or economic phenomena or areal series. The simplest way of indicating values referring to the individual areas is by figures written over them. However, it is also possible to express the differences in values between areas by shades of colours. In such a case it is advisable to progress from lighter to darker colours with the increasing intensity of the phenomenon examined, and it all should be clearly explained in an attached legend that also provides information on the measurable values of the phenomenon studied. In the case of cartograms one must always be careful to make it clear to readers what geographical area is shown in the cartogram, especially, if it can be assumed that the target readership is not familiar with it.



Figure 2. The geographical area covered in Europe standardized mortality rate for all causes, all ages per 100 000 population in 1990. Source: *Year 1990 Health for all* (London).

Figure 28: The structure of a cartogram

In many cases cartograms are combined with bar charts, pie charts or other types of charts to create **cartodiagrams**, which can make statistical diagrams more picturesque. Cartodiagrams are suitable for displaying areal series connected on the basis of geographical dimensions. That is why it is a mode of statistical representation applicable also in complex analyses.

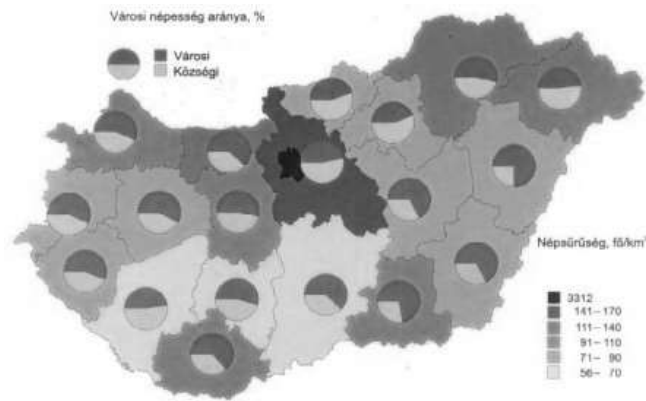


Figure 29: Example illustrating the structure of a cartodiagram

Cartodiagrams are not to be confused with **dot distribution maps**, which are also suitable for illustrating areal series but the number and density of the dots refers to the size of the data belonging to a given geographical area.



Figure 30: Example illustrating the structure of a dot distribution map

9.5.6. Pictogram

Pictograms, or pictographs, are one of the simplest and most spectacular ways of statistical visual representation. The primary function of a pictogram is to attract attention and it is directly suitable for providing the widest strata of the population with statistical information. They must also comply with the requirements of areal proportionality, which, however, is extremely difficult, since proportions between the phenomena investigated are easier to illustrate than to determine precisely. Provided the proportion between the phenomena studied may be expressed by a whole number, it is advisable to multiply the size of the original

pictogram. Next to the pictograms the numerical figures of the phenomena must also be displayed.



Figure 31: Example illustrating the structure of a pictogram

9.5.7. Complex statistical charts

In the following part some types of charts which are only rarely used in practice although they are usually mentioned during theoretical statistical studies are briefly dealt with. The application of complex statistical diagrams is recommended as working charts or in the presentation of research results to make the publications even more interesting.

In preparing a radar chart individual statistical phenomena are represented by equi-angular spokes beginning from one central point. The data placed at distances from the central point proportional to their sizes are indicated by dots on the given spokes (radii) and by connecting these points a cobweb shape is created. It is suitable mainly to illustrate the changes of data of different characters but in certain cases it may also characterize periods of time. This statistical mode of presentation is difficult to prepare but very spectacular.

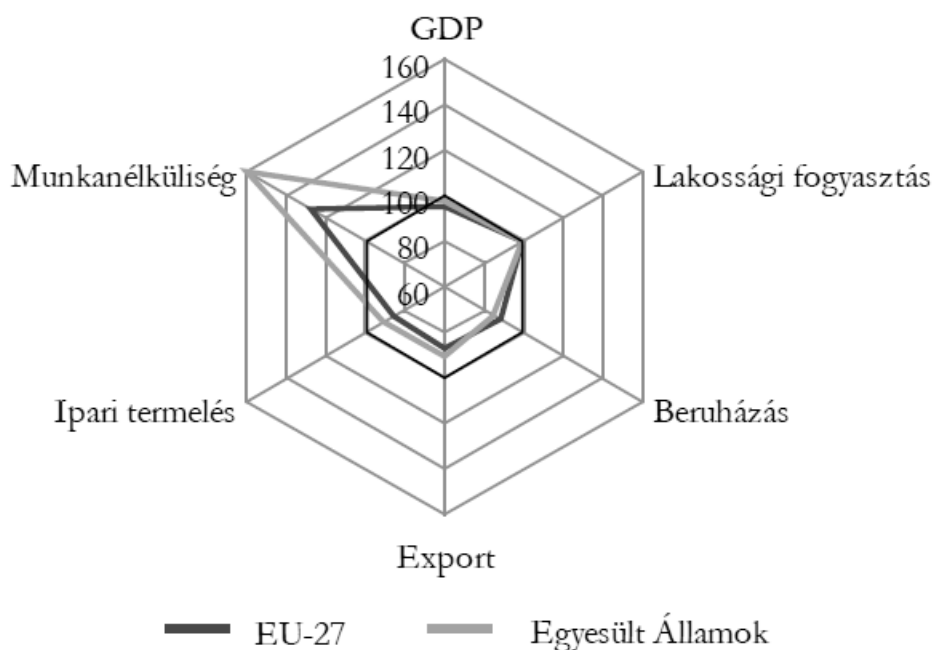


Figure 32: Example illustrating the structure of a radar chart

The stem-and-leaf display method is applied for interval visual analogue scale variables. The values of the variables are broken down to stems and leaves by their digits, where the first place value is usually the stem. Then the stems are sorted in ascending order and the leaves belonging to the same stems are also sorted row by row. The diagram thus obtained resembles a histogram and, as such, may also function as a working chart as from the shape of the distribution one can draw conclusions concerning the methods of the further statistical investigation.

The **box plot** is a very clear but at the same time very complex way of visual representation, which depicts quantitative criteria on the basis of quartiles. In the statistical chart the box, the middle 50 %, is placed on a line and the median is marked. The box plot can show how the middle 50 % of the sample is distributed around the median and it also indicates outliers.

3. ábra. Az egy főre jutó GDP box-plot ábrája a megyékben, Budapesttel és anélkül, 1999

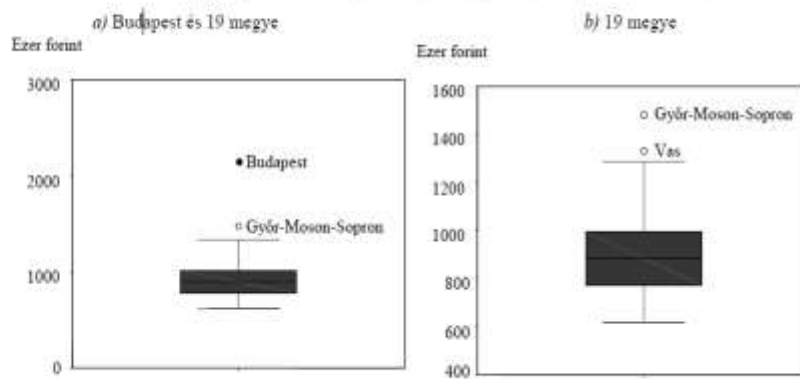


Figure 33: Example illustrating the structure of a box plot

Cluster analysis is used in economic statistics and it involves creating homogenous groups of data, called clusters. The data within the clusters are similar to one another according to some of their characteristics, which differentiate them from the elements of other clusters. This mode of graphic representation is suitable for showing spectacularly the relationships of the clusters to one another according to some given dimensions and they may also be suitable for displaying further dimensions by visualizing the individual clusters and their sizes. Clusters can also be created from simple point charts, in which case the characteristic that form the basis of separation must be clearly indicated as well as the borders of the individual clusters.

4. ábra. A klaszterek relatív pozíciója társadalmi státusz és háztartási jövedelem szerint, 2010

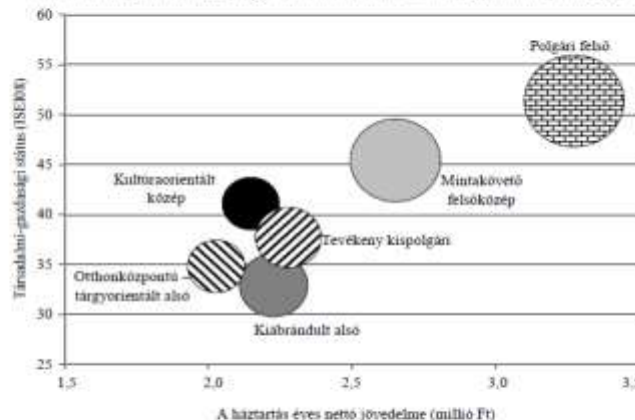


Figure 34: Example illustrating the representation of clusters

Of course, the presentation of complex statistical charts is not complete here but the focus of this work is on those that one may encounter in everyday life. However, it must be noted that the science of statistics knows and uses numerous other types of statistical diagrams.

9.6. CONCLUSION

As a conclusion it may be said that graphical representation is an important and indispensable element of statistics, a concise summary of the various phases of statistical work. As a result of the rapid development of the Internet and the graphical performances of computers, tablets and smart phones, charts are a part of everyday life now, since due to an increased demand for information huge quantities of information reach people by statistical diagrams these days. To be able to convey and to comprehend that information it is indispensable for everyone to learn about the rules of their design, especially the possibility of distortion inherent in graphical representation. Statistical charts, as working charts, also help statisticians in certain phases of their work; they assist their decisions on how to proceed with their investigations. When creating charts it is important to comply with the principles of graphical representation; in spite of the fact that state-of-the-art software may often offer more spectacular solutions, it does not necessarily improve the ability of statistical charts to convey information and interpreting them may not become easier either. Having chosen the most appropriate type of diagram of those presented above, one must not forget the rules of chart design: one must design clear and well-arranged diagrams, which depict one phenomenon if possible, and the same diagram type must be used for presenting the same phenomena in order to assist the reader.

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