STABILITY PACT
FOR SOUTH EASTERN EUROPE

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT

A Handbook for Teachers, Researchers and Health Professionals

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Preface

This books' title „Health Systems and Their Evidence Based Development" comprises some key features of health care in the 21st century:

1) The organisation of health care delivery is of utmost importance for the post-modern state in Europe and North-America as it is - in a different way - for the developing world. This is the case because of its economic importance signified by the spending of between 5 and 15% of the Gross Domestic Product for health but even more because of the growing relevance of excellent population health for economic development in low-tension open societies (1);

2) Modern health systems are not to be looked at as static structures, the best example being provided by the German Bismarckian System which maintained for more than hundred years i.e. since 1883, some essentials like the obligatory membership (up to an income threshold for high earners), a multiplicity of fee-based health insurances, and the sharing of the contributions between employers and employees (2). Today health care systems undergo continuous reform, mainly to curb expenditure but also to guaranty access and quality of service to everybody (see for example the Dubrovnik Pledge of the Ministers of Health in South East Europe in 2001 (3) or the conclusions at the Ljubljana Conference in 1996 (4)). One example of this is the existence of long waiting queues for specific operations for hip or knee replacements in the tax-based Beveridge Systems especially in northern Europe.

3) Health systems reform and development, however, require thorough scientific analysis to identify the options available to the politician. The term coined for this demand in today's discussion refers to the evidence base of decision making (see WHO-EURO 2003 (5)). Unfortunately still the reform legislation in most countries orients towards the uni-dimensional consideration of financial constraints, missing the chance of exploring real improvement and instead modifying repeatedly the various models of co-payment.

4) The title refers implicitly to a comparative approach between national health systems. Especially in Europe with her different historical lines of development this is an essential element if the European unification process is taken into account. Only recently the European High Court has issued strategic decisions on the universal access to health care in the European Union wherever a patient seeks care and wherever she or he is insured. A public health mandate of the European Commission has been formulated already in the Maastricht treaty of 1992 (6). Converging trends can also be recognized with regard to the development of „mixed" systems containing elements of the Bismarck as well as of the Beveridge model.

As this handbook is devoted to all teachers, researchers, postgraduate students and professionals in the health field the question arises who in the end is responsible for the organization and further development of the health system. The answer can only be that this field is essentially characterized by multi-professionality and inter-disciplinarity comprising all parties including the patients and the population themselves. However, the steering of such systems, the balancing of input and output, and their evaluation are mainly considered to be subject to the health sciences, i.e. a part of the public health. Therefore it is not by chance, that this handbook has been developed in the context of a Research & Development project in order to enable and improve the teaching for research and practice in Public Health: The Public Health Collaboration in South Eastern Europe (PH-SEE), funded since the year 2000 by the Stability Pact through the German Academic Exchange Service (DAAD). On the PH-SEE website (7) maintained by the Andrija Štampar School of Public Health in Zagreb, Croatia, the abstracts of teaching modules in a number of public health fields can directly be accessed like „Methods and Tools in Health Sciences", „Determinants of Health", „Disease Prevention and Health Promotion", „Health Care and Health Services" or „Public Health Strategies" and in addition the chapters of this handbook in full text.

This handbook is likely to be the first compendium on the main issues in evidence based health systems development with a focus on the situation and the experience in South Eastern Europe, and more general in all of the former socialist economies in transition, most of them in a process of accession to the European Union.

The book comprises three main chapters: (1.0) Health Systems Analysis, (2.0) Health Systems Management and (3.0) Health Policy. This agenda describes the full cycle of scientific analysis and evaluation, the operational steering of the system, and the developmental aspects of change and reform. Within these three sections the reader finds basic texts in the format of teaching modules including exercises for students and reference material, complemented by case studies for study work. Deliberately the conceptual approach of this handbook goes beyond the usual listing of topics to be dealt with in teaching public health as it is obvious that most readers would expect and need more than a reference to knowledge and expertise elsewhere. Thus the volume can be used as a teaching book as well as a compendium or handbook in the field. It corresponds to a total student workload of 12 ECTS (European Credit Transfer System) and its contents may be combined with other modules. Other handbooks will follow this first edition covering the areas listed above as on the website (7).

Finally as the principle investigators of the Public Health

Collaboration in South Eastern Europe we have to express our sincerest thanks to the editors and authors for their dedication and patience and an enormous amount of unpaid work, which gave this endeavour a special flavour and unique value. May this cooperative work also serve as an example for a brighter future in a war-torn region and the re-establishment of cooperation and peace building, collegiality and togetherness in the service to the people.

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HEALTH SYSTEMS ANALYSIS

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**The Role and Organization of Health Care Systems**
Module: 1.1	**ECTS (suggested): 0.75**
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Keywords	Health care; health systems; health systems organization and performance; primary health care; hospital care; health care reforms
Learning objectives	After this module, students and health professionals should: • increase understanding of health care systems organization, their historical development and respective functions; • distinguish national health care systems based on sources of funding (Beveridge, Bismarck and Private Insurance model); • be able to describe scope of activities of health organizations on different levels (self care, primary, secondary and tertiary level of care); • be able to classify health service organizations depend on various criteria (type of service, length of stay, type of control or ownership); • describe three generations of reforms in health system; • identify main goals and objectives of national health systems; and • identify common problems and new challenges of health care systems.
Abstract	The health of the people is always a national priority. Health Care System (HCS) infrastructure includes services, facilities, institutions/establishments, organizations, and those operating them for conducting the delivery of a variety of health programmes. They provide individuals, families, and communities with health care, which consists of a combination of promotive, protective, preventive, diagnostic, curative and rehabilitative measures. HCS are different all over the world and strongly influenced by each nation's unique history, traditions, socio-cultural, economic, political and other factors. But, regardless of all present differences, there are still some common characteristics, typical for all HCS. In this module three levels of healthcare (primary, secondary, tertiary) are described, as well as their historical development. Concerning sources of funding, main models of National HCS are: the Beveridge model, the Bismarck model and the Private Insurance model. HCS are continuously evolving. There are presented three generations of HCS reforms. Improvement of population's health is often expressed as improved coverage, access, equity, quality of care, but also efficiency in use of resources, and financing. HCS facing new challenges, among them are aging of the population, medical technology innovations, pressure to constraint costs, community involvement and intersectoral action. Those principles will be important more then ever.

Teaching methods	Teaching methods include lectures and interactive group discussion.
Specific recommendations for teacher	This module should be organized within 0.75 ECTS, out of which one third are lectures and group discussion supervised by the lecturer. The rest is individual work (searching Internet mainly) in order to prepare seminar paper.
Assessment of Students	Assessment should be based on the quality of seminar paper, which presents the national health system of the students' country. Oral exam is also recommended.

THE ROLE AND ORGANIZATION OF HEALTH SYSTEMS

Dončo Donev

Introduction

Health systems have a vital and continuing responsibility to people throughout the lifespan. They are crucial to the healthy development of individuals, families and societies everywhere. The real progress in health towards the United Nations Millennium Development Goals* and other national health priorities depends vitally on stronger health systems based on primary health care (1).

Improving health is clearly the main objective of each health system, but it is not the only one. The objective of good health itself is really twofold: the best attainable average level – *goodness* - and the smallest feasible differences among individuals and groups – *fairness*. Goodness means a health system responding well to what people expect of it, and fairness means it responds equally well to everyone, without discrimination (2).

Each national health system should be directed to achieve three overall goals: *good health, responsiveness to the expectations of the population,* and *fairness of financial contribution.* Progress towards them depends crucially on how well systems carry out four vital functions. These are: *service provision, resource generation, financing* and *stewardship*. Comparing the way these functions are actually carried out provide a basis for understanding performance variations over the time and among countries. There are minimum requirements which every health care system should meet equitably: access to quality services for acute and chronic health needs; effective health promotion and disease prevention services; and appropriate response to new threats as they emerge (emerging infectious diseases, growing burden of non-communicable diseases and injuries, and the health effects of global environmental changes) (1,2).

The overall mission of WHO is the attainment by all people of the highest possible level of health, with special emphasis on closing the gaps

* The goals in the area of development and poverty eradication (to reduce poverty and hunger and to tackle ill-health, gender inequality, lack of education, access to clean water and environmental degradation). These goals are included in the United Nations Millennium Declaration adopted at the Millennium Summit in New York in September 2000, and are now widely referred to as Millennium Development Goals.

within and among countries. The ability of WHO to fulfill this mission depends greatly on the effectiveness of health systems in Member States – and strengthening those systems is one of WHO's four strategic directions. It connects very well with the other three: reducing the excess mortality of poor and marginalized populations; dealing effectively with the leading risk factors; and placing health at the center of the broader development agenda because population health contributes crucially to economic and social development (1,3).

Health systems have contributed enormously to better health for most of the global population during the 20th century. Today, health systems, in all countries, rich and poor, play a bigger and more influential role in people's lives than ever before. Health systems of some sort have existed for a long as people have tried to protect their health and treat diseases. Traditional practices, often integrated with spiritual counseling and providing both preventive and curative care, have existed for thousands of years and often coexist today with modern medicine. Many of them are still the treatment of choice for some health conditions, or are resorted to because modern alternatives are not understood or trusted, or fail, or are too expensive. Health systems have undergone overlapping generations of reforms in the past 100 years, including the founding of national health care systems and the extension of social insurance schemes. Later came the promotion of primary health care as a route to achieving affordable universal coverage – the goal of health for all. In the past decade or so there has been a gradual shift of vision towards what WHO calls the „new universalism". Rather than all possible care for everyone, or only the simplest and most basic care for the poor, this means delivery to all of high-quality essential care, defined mostly by criteria of effectiveness, cost and social acceptability. This shift has been partly due to the profound political and economic changes of the last 20 years or so. These include the transformation from centrally planned to market-oriented economies, reduced state intervention in national economies, fewer government controls, and more decentralization (2).

Within all systems there are many highly skilled, dedicated people working at all levels to improve the health of their communities. As the new century began, health systems have the power and the potential to achieve further extraordinary improvements. Unfortunately, health systems can also misuse their power and squander their potential. Poorly structured, badly led, inefficiently organized and inadequately funded health systems can do more harm than good. The ultimate responsibility for the overall performance of a country's health system lies with government, which in turn should involve all sectors of society in its stewardship. The careful and responsible management of the well-being of the population is the very essence of good government. For

every country it means establishing the best and fairest health system possible with available resources. The health of the people is always a national priority and the government responsibility for it should be continuous and permanent. Ministries of health must therefore take on a large part of the stewardship of health systems. Healthy policy and strategies need to cover the private provision of services and private financing, as well as state funding and activities. Only in this way can health systems as a whole be oriented towards achieving goals that are in the public interest (2).

Health care services and health services organizations

Health care is the comprehensive social effort, organized or not, private or public, that attempts to guarantee, provide, finance, and promote health. Health care consists of measures, activities and procedures for maintaining and improvement of health, living and working environment, as well as measures, activities and procedures which are undertaken in the field of health care for maintaining and improvement of people's health; prevention and control of specific diseases; early detection of the diseases and conditions of ill health, timely and efficient treatment and rehabilitation. It changed markedly during the 20th century moving toward the ideal of wellbeing and prevention of disease and disability. Delivery of health care services involves the organized public or private efforts that assist individuals primarily in regaining health, but also in preventing disease and disability (2,4).

Delivery of services to patients / consumers occurs in a variety of organizational settings ("patient" is anyone served by health services organization). Health services is a permanent countrywide system of established institutions, the multipurpose objective of which is to cope with the various health needs and demands of the population and thereby provide health care for individuals and the community, including a broad spectrum of preventive and curative activities. All health services organizations can be classified by ownership and profit motive. In addition, they can be classified by whether the patient is admitted as an inpatient or outpatient and, for an inpatient, by the average length of stay (4,5).

Historically, hospitals and nursing facilities have been the most common and dominant health services organizations engaged in delivery of health services. They remain prominent in the contemporary health care systems, but other health services organizations have achieved stature. Among them are outpatient clinics, imaging centers, free-standing urgent care and surgical centers, large group practices, and home health agencies. Multi-organizational systems,

both vertically and horizontally integrated, are widespread. These various health services organizations and others face new environments containing a wide range of external pressures, including new rules and technologies, changed demography, accountability to multiple constituents, and constraints on resources. As a result, health services organization must allocate and use resources more effectively and strive for continuous improvement and continued excellence in an increasingly restrictive environment (5).

What is a health system?

In today's complex world, it can be difficult to say exactly what a health system is, what it consists of, and where it begins and ends. Health system includes all the activities, which primary purpose is to promote, restore and maintain health. It means that the health system is the complex of interrelated elements that contribute to health in homes, educational institutions, workplaces, public places, and communities, as well as in the physical and psycho-social environment and the health and related sectors. A health system is usually organized at various levels, starting at the most peripheral level, also known as the community level or the primary level of health care, and proceeding through the intermediate (district, regional or provincial) to the central level. The intermediate and central levels deal with those elements of the health system that provide progressively more complex and more specialized care and support. It is not easy to conceive such multifaceted health system, to maintain its cohesion and to ensure that it functions in compliance with agreed policies. A comprehensive health system denotes one that includes all the elements required to meet all the health needs of the population. Health system infrastructure includes services, facilities, institutions or establishments, organizations, and those operating them for conducting the delivery of a variety of health programmes. They provide individuals, families, and communities with health care that consists of a combination of promotive, protective, preventive, diagnostic, curative and rehabilitative measures. Health resources are all the means of the health care system available for its operation, including manpower, buildings, equipment, supplies, funds, knowledge and technology. Health sector includes governmental ministries and departments, organizations and services, social security and health insurance schemes, voluntary organizations and private individuals and groups providing health services. Intersectoral action is an action in which the health sector and other relevant sectors collaborate for the achievement of a common goal, the contributions of the different sectors being closely coordinated. Multisectoral action is synonymous term to the intersectoral action. The former (intersectoral) perhaps emphasizing the

element of coordination, the latter (multisectoral) the contribution of a number of sectors (4,6).

Health systems are defined by WHO as comprising all the organizations, institutions and resources that are devoted to producing health actions. A health action is defined as any effort, whether in personal health care, public health services or through intersectoral initiatives, whose primary purpose is to improve health (2,6).

Formal health services, including the professional delivery of personal medical attention, are clearly within these boundaries. So are actions by traditional healers, and all use of medication, whether prescribed by a provider or not. So is home care of the sick, which is how somewhere between 70% and 90% of all sickness is managed. Such traditional public health activities as health promotion and disease prevention, and other health-enhancing interventions like road and environmental safety improvement, are also part of the system. Beyond the boundaries of this definition are those activities whose primary purpose is something other than health – education, for example – even if these activities have a secondary, health-enhancing benefit. Hence, the general education system is outside the boundaries, but specifically health-related education is included. So are actions intended chiefly to improve health indirectly by influencing how non-health systems function – for example, actions to increase girls' school enrolment or change the curriculum to make students better future caregivers and consumers of health care (2,6).

Nearly all the information available about health systems refers only to the provision of, and investment in, health services: that is, the health care system, including preventive, curative and palliative interventions, whether directed to individuals or to populations. Efforts are needed to quantify and assess those activities implied by the wider definition, so as to begin to gauge their relative cost and effectiveness in contributing to the goals of the health system. Even by this more limited definition, health systems today represent one of the largest sectors in the world economy. Global spending on health care was almost 8% of world gross domestic product (GDP), in 1997 (2).

With rare exceptions, even in industrialized countries, organized health systems in the modern sense, intended to benefit the population at large, barely existed a century ago. Hospitals have a much longer history than complete systems in many countries. Until well into the 19th century they were for the most part run by charitable organizations, and often were little more than refuges for the orphaned, the crippled, the destitute or the insane. And there was nothing like the modern practice of referrals from one level of the system

to another, and little protection from financial risk apart from that offered by charity or by small-scale pooling of contributions among workers in the same occupation. Towards the close of the 19th century, the industrial revolution was transforming the lives of people worldwide. At the same time societies began to recognize the huge toll of death, illness and disability occurring among workers, whether from infectious diseases or from industrial accidents and exposures. About the same time, workers' health was becoming a political issue in some European countries, but for quite different reasons. Bismarck, Chancellor of Germany, in 1883, enacted a law requiring employer contributions to health coverage for low-wage workers in certain occupations, adding other classes of workers in subsequent years. This was the first example of a state-mandated social insurance model. The popularity of this law among workers led to the adoption of similar legislation in Belgium in 1894, Norway in 1909, Denmark in 1935 and in Netherlands a few years later. The influence of the German model began to spread outside Europe after the First World War (in 1922, Japan, in 1924, Chile) (2,7).

In the late 1800s, Russia had begun setting up a huge network of provincial medical stations and hospitals where treatment was free and supported by tax funds. After the Bolshevik revolution in 1917, it was decreed that free medical care should be provided for the entire population, and the resulting system was largely maintained for almost eight decades. This was the earliest example of a completely centralized and state-controlled model.

Not least among its effects, the Second World War damaged or virtually destroyed health infrastructures in many countries and delayed their health system plans. Paradoxically, it also paved the way for the introduction of some others. Wartime Britain's national emergency service to deal with casualties was helpful in the construction of what became, in 1948, the National Health Service, perhaps the most widely influential model of a health system. The Beveridge Report of 1942 had identified health care as one of the three basic prerequisites for a viable social security system. The government's White Paper of 1944 stated the policy that „Everybody, irrespective of means, age, sex or occupation shall have equal opportunity to benefit from the best and most up-to-date medical and allied services available", adding that those services should be comprehensive and free of charge and should promote good health, as well as treating sickness and disease (2,7).

Today's health systems are modeled to varying degrees on one or more of a few basic designs that emerged and have been refined since the late 19th century. One of these aims to cover all or most citizens through mandated employer and employee payments to insurance or sickness funds, while pro-

viding care through both public and private providers. Much debate has centered on whether one way of organizing a health system is better than another, but what matters about a system's overall structure is how well it facilitates the performance of its key functions.

Models of national health care systems based on the sources of funding

Based on the source of their funding, three main models of national healthcare systems can be distinguished: the Beveridge model, the Bismarck model and the Private Insurance model (7,8,9) (Table 1).

Table 1. Three main models of health care systems based on the sources of funding (7,8,9)

Model of Health Care System	Country in which the model exists	Source of funding	Type of providers
Beveridge model	UK, Ireland, Sweden, Norway, Finland, Denmark, Spain, Portugal, Italy, Greece, Canada, Australia	Taxation (State Budget) Universal scope (all citizens) Not related to income	Public: - Predominantly public providers and governmental ownership - National Health Service - Complete coverage with basic health benefits and free access to all citizens
Bismark model	Germany, Holland, Belgium, France, Austria, Switzerland, Israel, Japan, CSEE and FSU countries	Compulsory health insurance premiums paid by employers and employees Selective scope Related to income	Mixed: - Public and private providers with dominant social ownership - Coverage of 60-80% with basic insurance „basket" of health services
Private insurance model	USA	Predominantly private insurance and funding Medicare Medicaid	Predominantly private providers Managed care

The Beveridge „public" model was inspired by the William Beveridge Report for social insurance presented in the English Parliament in 1942. Funding is based mainly on taxation and is characterized by a centrally organized National Health Service where the services are provided by mainly public health providers (hospitals, community GPs, specialists and public health services). In this model, healthcare budgets compete with other spending priorities. The countries using this model, beside United Kingdom, are Ireland, Sweden,

Norway, Finland, Denmark, Spain, Portugal, Italy, Greece, Canada and Australia.

The Bismarck „mixed" model was inspired by the 1883 Germany Social Legislation and National Health Insurance Plan for workers introduced by Otto von Bismark, the Chancellor of Germany. Funds are provided mainly by premium-financed social/mandatory insurance and, beside Germany, is found in countries such as Holland, Belgium, France, Austria, Switzerland, Israel, Japan, Central and South East European (CSEE) countries and Former Soviet Union (FSU) countries. Also Japan has a premium-based mandatory insurance funds system. This model results in a mix of private and public providers, and allows more flexible spending on healthcare.

The „private" insurance model is also known as the model of „independent customer". Funding of the system is based on premiums, paid into private insurance companies, and in its pure form actually exists only in the USA. In this system, the funding is predominantly private, with the exception of social care through Medicare and Medicaid. The great majority of providers in this model belong to the private sector.

All three models of health care are imperfect and expensive, too. All healthcare systems are aiming at „perfection", i.e. they try to achieve an optimal mixture of access to healthcare, quality of care and cost efficiency.

According to the World Health Organization (WHO), the healthcare systems present in different countries are strongly influenced by the underlying norms and values prevailing in the respective societies. Like other human service systems, health care services often reflect deeply rooted social and cultural expectations of the community. Although these fundamental values are generated outside the formal structure of the healthcare system, they often define its overall character and capacity. Healthcare systems are therefore different all over the world and are strongly influenced by each nation's unique history, traditions and political system. This has led to different institutions and a large variation in the type of social contracts between the citizens and their respective governments.

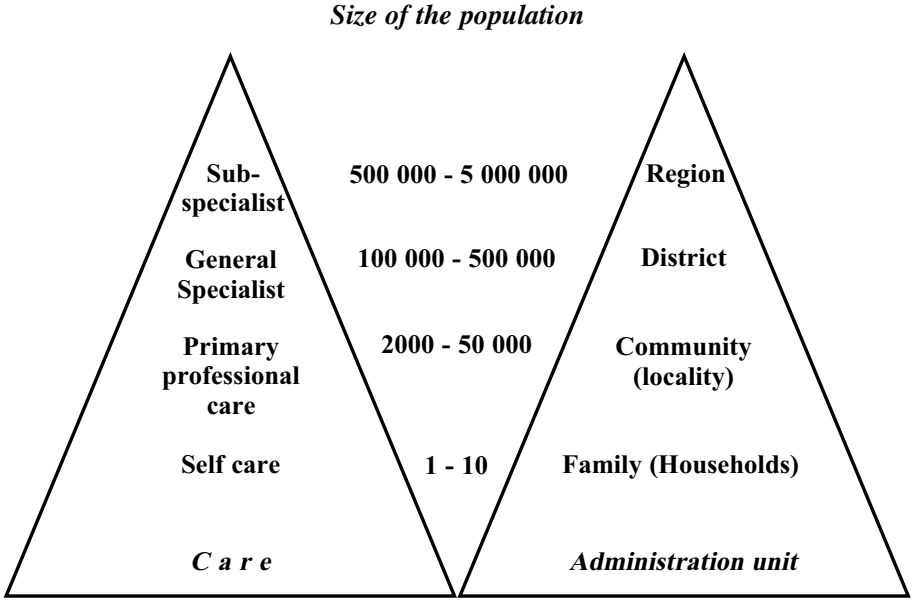
In some societies, healthcare is viewed as a predominantly social or collective good, from which all citizens belonging to that society should benefit, irrespective of whatever individual curative or preventive care is needed. Related to this view is the principle of solidarity, where the cost of care is cross-subsidized intentionally from the young to the old, from the rich to the poor and from the healthy to the diseased.

Other societies, more influenced by the market-oriented thinking of the 1980s, increasingly perceive healthcare as a commodity that should be bought and sold on the open market. These marketing incentives possibly allow a more dynamic and greater efficiency of healthcare services and a better control of growth in health care expenditure. But, nowadays, this concept, which perceive health care services as a commodity does not prevail in Europe.

Levels of organization of health care systems and health care delivery

All models of health care systems are imperfect and there is no a model which is the best and broadly accepted and recommended. There are big differences among countries in relation to the goals, structure, organization, finance and the other characteristics of the health care systems. These differences are influenced by history, traditions, socio-cultural, economic, political and other factors. But, regardless of all present differences, there are same common characteristics, typical for all organized health care systems. First of all those characteristics relate to the so called „levels of health care". In accordance with the size of the population served, and specificities of the diseases and conditions treated at certain level, as well as with some organizational characteristics, it is possible to recognize four levels of the health care system and health care delivery (7,9,10,11,12,13,14,15) (Figure 1).

Figure 1. Levels of Care within the Health Care System



Self care is the first level, which is nonprofessional care. It is performed within the family, and the population group counts from one to 10 persons. Self-care implies largely unorganized health activities and health-related decision-making carried out by individuals, families, neighbors, friends and workmates. These include the maintenance of health, prevention of disease, self-diagnosis, self-treatment, including self-medication, and self-applied follow-up care and social support to the sick and weak members of the family after contact with the health services. By community involvement and participation, individuals and families accept responsibility for their, and the community's health and welfare and develop the capability to contribute to their own and the community's development (4). This type of care has its own long tradition and it is a part of all cultures. WHO has shown interest and pointed out that traditional and alternative medicine consist big potential, which might be useful for improvement of the health status of the population. WHO strategy „Health for all" and the concept of Primary Health Care paid an appropriate attention to self care and need for health education of the individuals, family and population as a whole in order to enable and to empower them in taking responsibilities and making decisions about their own health and the factors which influenced the health (6,11,15).

Health promotion advice on important lifestyle issues such as nutrition, exercise, consumption of alcohol and cessation of smoking is most effective if it is persistent, consistent and continuous, and if it is offered to families and communities at all levels. Within this population context, individual advice can be given on an opportunistic basis to those who attend health services for whatever reason (6,16).

Primary professional (medical) care is a care of the „first contact" of the individual with the health care service, which is provided in ambulatory settings by qualified health professionals (general practitioner-GP, family doctor, or nurse) when a patient came, usually for the first time, with certain symptoms or signs of disease. The primary professional level of care includes a doctor and members of its team: nurse, birth attendant, home visiting nurse, social worker, and sometimes a physiotherapist, too. The administration/territorial unit for this type of care is a local community, and the population size vary from 2000 persons per one GP or family doctor to 10000 - 50000 inhabitants per health facility within the community/municipality (health station, health center). Beside medical care (diagnostics, treatment and rehabilitation) the primary professional care team performs various activities toward maintenance and improvement of the health and prevention of diseases. The most common role of the physician is „gate keeper", which means that the doctor is motivat-

ed and empowered to treat and cure broader scope of illnesses and conditions (up to 85% of health care problems in a community without recourse to specialist), and to select and refer patients to higher levels of the health care system when necessary.

Secondary or intermediate level of care is general specialist care, delivered by „general specialist doctor" for more complex conditions, which could not be resolved by the general practitioner or primary professional care level. General specialists (surgeons, internal medicine specialists, gynecologists, psychiatrists etc.) usually deliver this type of care through specialized services of district or provincial „general hospitals". The administrative unit for secondary level of care is a district, and the population size is from 100000 to 500000 inhabitants. Usually patient is directed by the general practitioner from primary professional level to the secondary level as the first referral level of care through referral.

Tertiary or central level of care is sub-specialist care including highly specific services, which might be delivered in specialized institutions or by highly specialized health professionals - sub-specialists i.e. neurosurgeons, plastic surgeons, nephrologists, cardiologists etc. The specialized institutions, which provide this type of care are, also, educational institutions for health manpower (university hospitals, university clinics, etc.). The administrative unit for tertiary level of care is a region, and the population size is from 500000 to 5000000 inhabitants. In some countries, mainly developing countries, this level of care is the same as the national level. A patient should be referred to this level from primary or secondary level of care.

Secondary and tertiary care support Primary health care by providing technologically-based diagnosis, treatment and rehabilitation. WHO recommends that in most Member States, secondary and tertiary care should more clearly serve and support primary care, concentrating on those functions that cannot be performed effectively by the latter. Planning secondary and tertiary care facilities in accordance with the principle of a population-based „regionalized" system allows for more rational use of expensive technologies and of the expertise of highly trained personnel (6).

Typical functions of the overall health care system are:

- Health services (environmental, health promotion, prevention of diseases and injuries, primary care, specialist medicine, hospital services, services for specific groups, self-help);
- Financing health care (mobilization of funds, allocation of finances);

- Production of health resources (construction and maintenance of health facilities, production and distribution of medicines, production, distribution and maintenance of instruments and equipment);
- Education and training of health manpower (undergraduate training, post-graduate training);
- Research and development (health research, technology development, assessment and transfer, quality control);
- Management of a National Health System (policy and strategy development, information, coordination with other sectors, regulation of activities and utilization of health manpower, physical resources and environmental health services).

The main objectives of each national health system should be (7): 1) universal access to a broad range of health services; 2) promotion of national health goals; 3) improvement in health status indicators; 4) equity in regional and socio-demographic accessibility and quality of care; 5) adequacy of financing with cost containment and efficient use of resources; 6) consumer satisfaction and choice of primary care provider; 7) provider satisfaction and choice of referral services; 8) portability of benefits when changing employer or residence; 9) public administration or regulation; 10) promotion of high quality of service; 11) comprehensive in primary, secondary, and tertiary levels of care; 12) well developed information and monitoring systems; 13) continuing policy and management review; 14) promotion of standards of professional education, training, research; 15) governmental and private provision of services; and 16) decentralized management and community participation.

Outpatient Care

Outpatient care is very important part of the health care system representing the first contact of the consumer with the professional health care and the first step of a continuous health care. Outpatient care is delivered to a „moving" patient (not tight to bed), through institutions in which the consumer come for a short visit for consultation, examination, treatment and follow-up, usually once a week or rarely, and in the most of the cases, the contact is realized with an individual health worker. Such kind of services and institutions might be a part of the hospital, community health center or certain polyclinic and dispensaries (4,10,13,15).

Historically beginnings of outpatient care appeared in 16th century, when medical care organized mainly through in-patient institutions connected

to churches and monasteries started to change and move to be under the state authorities. Differentiation within the medical profession started by dividing the doctors into two basic groups: the first group continue to be tighten to hospitals, but delivering also outpatient services from the position of specialists or consultants, and the other group of doctor were oriented to work in out-patient offices for poor or in doctor's offices with advanced payment for treatment for defined period of time, usually for a week. In that way started differentiation of the profession, which is a synonym for outpatient care – a general practitioner. An official Act on health insurance was adopted in Great Britain in 1911 and a doctor of general medicine or general practitioner was authorized as a main provider of outpatient care, usually through independent doctor's offices for general medicine and, later on, through health centers. The importance of the outpatient care and responsibility of the governments for improving the health status of the population in their own countries was emphasized by WHO at the historical Conference on Primary Health Care, held in Alma Ata in 1978, based on the core principles of primary health care formulated in the Declaration of Alma Ata: universal access and coverage on the basis of need; health equity as part of development oriented to social justice; community participation in defining and implementing health agendas; and intersectoral approach to health (7,17).

Primary health care is essential health care made universally accessible to individuals and families in the community by means acceptable to them and at a cost the community and country can afford, with methods that are practical, scientifically sound and socially acceptable. Everyone in the community should have access to it, and everyone should be involved in it. It means that „people have the right and duty to participate individually and collectively in the planning and implementation of their health care. Related sectors should also be involved in it in addition to the health sector. At the very least, it should include education of the community on the health problems prevalent and on methods of preventing health problems from arising or of controlling them; the promotion of adequate supplies of food and of proper nutrition; sufficient safe water and basic sanitation; maternal and child health care, including family planning, the prevention and control of epidemic and locally endemic diseases; immunization against the main infectious diseases; appropriate treatment of common diseases and injures; and the provision of essential drugs. Primary health care is the central function and main focus of a country's health system, the principal vehicle for the delivery of health care, the most peripheral level in a health system stretching from the periphery to the centre, and an integral part of the social and economic country development. The form it takes will vary according to each country's political, economic, social, cultural and

epidemiological patterns. The relationship between patient care and public health functions is one of the defining characteristics of the primary health care approach (1,4,17).

Outpatient institutions and services

There is a variety of organizational forms of the outpatient care across the world. The main objective of the outpatient care is to reduce hospitalization and to provide treatment of diseases and injuries in much cheaper conditions, whenever it is possible. The outpatient departments of hospitals were the first institutions described which are still available nowadays. They provide services in some urgent and life threatening conditions, in some acute diseases that require urgent intervention, in chronic diseases that require follow-up and control measures, as well as act as a referral level for primary health care or make decision for hospital admission when necessary.

The reorganization and reform of the outpatient care, after establishment of the Ministry of Health in Great Britain, in 1919, was directed toward creating a new institution of outpatient care so called Health Center. Health Center, in accordance with the Bertrand Dawson's Commission for health care reform in Great Britain in 1920s, is an institution which is responsible to integrate preventive and curative activities, to provide health care to the population living within certain territorial units, and to collaborate with the local authorities for all issues related to the health of the population. Additional equipment for laboratory and x-ray diagnostic services within the health center should be available, as well as general practitioners and nurses for team work. And, later on, in 1948, when National Health Service in Great Britain was established, the general practitioner became the most important gate-keeper at the entrance to the other levels of health care system. The development of health centers in Great Britain was facilitated by the act on family doctor, adopted in 1966. The idea for establishing health centers for outpatient care was accepted in many European countries, especially in former Soviet Union after the Bolshevik Revolution (2,7).

After the Alma Ata Conference, held in 1978, Primary Health Care became more and more important part of the health care system in each country – member of WHO. Even health services continued to have various organizational forms in different countries the health center was the most typical institution for outpatient care.

The institutions for Primary health care have special importance playing a role as institutions of the „first contact" of the patient with health care

system. Beside primary medical services those institutions contribute to maintain and improve overall physical, mental and social health and well being of the individuals, groups and of the population as a whole. The institutions for primary health care provide individual and group practice/services delivered through health centres or independent outpatient doctor's offices, as well as within the home of the patient, school and workplace.

Consultative-specialist health care is an intermediary level of providing health care, between primary health care and hospital treatment, where in the shortest period of time all necessary examinations and analyses should be performed, and a decision should be brought whether the patient is going to be referred to hospital treatment, or sent back on the level of primary health care, usually with precise diagnosis and certain directions for further treatment.

Home care or „hospital at home" is treatment at home of the diseased, which includes examination, diagnostic procedures, therapeutic and rehabilitation measures. Home care, as alternative of stationary treatment is a combination of medical and non-medical treatment and a factor that connects primary and hospital health care. It should be conducted in an organized way by hospitals and in accordance with certain programmes, which in addition to health service include other factors, such as: social protection services, children's public care, health insurance and pension-invalidity insurance funds as well as local communities. Home visiting by a doctor and medical technicians in the function of home care should be performed in a series and successively, according to a programme defined by the same physician, and keeping evidence should be performed on special hospital-temperature lists, which are going to be a base for compensation of the performed tasks. Several researches have demonstrated that for about 30%, or even more, of the treated patients in hospitals there were no real indications for hospital treatment, which means that their treatment could successfully be conducted through introduction of „substitution policies" i.e. day care hospitals, ambulatory care or organized home care by hospitals if there is satisfactory standard for accommodation of the patient at home, under supervision of the team for primary health care (4,6).

Home visiting by a doctor and medical technician considered as an »emergency medical service« is performed without formerly determined plan and on a patient's call and are shown as individual services through ambulatory protocols and reports for the performed home visiting.

In-patient care and institutions

In-patient/hospital care means admission into hospital or other stationary health organization, including diagnosis, treatment and rehabilitation, with in-patient care and treatment of the most severely ill patients who cannot be treated in ambulatory-polyclinic institutions or at home. Stationary health organizations are institutions, which, in addition to supplying diagnosis, treatment and medical rehabilitation, also provide hospital accommodation, treatment, care and food. They include hospitals, nursing homes, health resorts and rehabilitation centers. Hospital is a health organization which provides consultative-specialist health care and accommodation, treatment and food for the patients in a certain area and for more types of diseases and for persons of all ages, or only for persons diseased from certain illnesses, or for certain group of citizens (4,10).

Hospitals have been present in a variety of forms for millennia. Almost 5,000 years ago, Greek temples were the first, but similar institutions can be found in ancient Egyptian, Hindu, and Roman societies. These „hospitals" were very different than the hospitals of today, and over the span of time they have gone through a dramatic evolution from temples of workship and recuperation to almhouses and pest houses and finally to sources of modern-day miracles. The word „hospital" comes from the Latin *hospitalis*. Although well regarded earlier in history, hospitals in the Middle Ages and later had unsavory reputations and primarily served the poor. Until well into the 20th century physicians provided charity care in hospitals but treated private (fee-for-service) patients at home. New medical technology made treatment efficient, especially with surgical intervention, and this focused attention on acute care hospitals. Treatment of private patients brought acute care hospitals new prestige and acceptance. This evolution was well underway by the 1920s as acute care hospitals became differentiated and specialized to organize and deliver an expanded scope of services. Many acute care hospitals were small and owned by physicians as a convenient way to hospitalize their patients (5,10).

Hospitals are institutions whose primary function is to provide diagnostic and therapeutic medical, nursing, and other professional services for patients in need of care for medical conditions. Hospitals have at least six beds, an organized staff of physicians, and continuing nursing services under the direction of registered nurses. The WHO considers an establishment a hospital if it is permanently staffed by at least one physician, can offer in-patient accommodation, and can provide active medical and nursing care (7).

By convention of common use, a general (community or district) hos-

pital is an acute care hospital that provide diagnoses and treatment for patients with a variety of medical conditions or for more than one category of medical discipline for general medical and surgical problems, obstetrics and pediatrics. The title is used whether the hospital is not for profit or for profit. A general hospital provides permanent facilities, including inpatient beds, continuous nursing services, diagnosis, and treatment, through and organized professional staff organization, for patients with a variety of surgical and non-surgical conditions. This is in contrast to special hospitals, which admit only certain types of patients by age or sex, or those with specified illnesses or conditions such as a children's, maternity, psychiatric, tuberculosis, chronic disease, geriatric, rehabilitation, or alcohol and drug treatment center which provide a particular type of service to the majority of their patients (5,7).

Hospital bed is any bed that is set up and staffed for accommodation and full-time care of in-patients and is situated in a part of the hospital where continuous medical care is provided. A bed census is usually taken at the end of a reporting period. The supply of hospital beds is measured in terms of hospital beds per 1000 population. This varies widely between and within countries. In addition closing of hospital beds is one of the difficult and controversial issues in health planning and health policies. It is even more difficult to close redundant or uneconomic hospital beds, because this means a loss of jobs in the community unless coupled with transfer of personnel to other services, itself a painful procedure. Total beds per 1000 population include all institutional beds utilized for in-patient medical care, but not geriatric custodial care. Acute care bed ratio is a more precise and comparable indicator representing the number of general, short-term care beds per 1000 population.

Hospitals are increasingly technologically oriented and costly to operate. Hospital services in the European Region underwent considerable expansion in during the 1960s, 1970s and the beginning of the 1980s but have since experienced increasing difficulties. Managing health systems with a fewer hospital days requires reorganization within the hospital to provide the support services for ambulatory diagnostic and treatment services as well as home care. The interactions between the hospital-based and community-based services require changes in the management culture and community-oriented approaches. Many developed countries are actively reducing hospital bed supplies, facilitating alternatives to hospital care, using incentive payments to promote day-hospital treatments, ambulatory and home care. In the more eastern part of the Region, the very large number of hospital beds (a legacy of health care policy in the past), combined with a severe economic crisis during the 1990s has created an extremely difficult situation characterized by dilapidated buildings,

worn-out equipment, lack of basic supplies and a financial inability to profit from new breakthroughs in hospital technology (6). During 1980s and 1990s in USA, especially in California, an intensive process of mergers or acquisitions of for-profit hospitals was taking place aimed to increase organization's capacity, financial viability and efficiency of the new unit, and ability for competition in its current markets (7,18).

Classification of hospitals

Hospitals are classified in several ways: *length of stay*, *type of service*, and *type of control or ownership*, as well as *size of the hospital* (4,5,6,7,10,12).

Length of stay is divided into acute care (short term) and chronic care (long term). Acute care (of short duration or episodic) is a synonym for short term. Chronic care (or long duration) is a synonym for long term hospitals. Short-term stay hospitals are those in which more than half of patients are admitted to units in the facility with an average length of stay shorter than 30 days. Long-term stay hospitals are those in which more than half of patients are admitted to units in the facility with an average length of stay of more than 30 days (7). The most of hospitals are short term. Community hospitals are acute care (short term). Rehabilitation and chronic disease hospitals, nursing homes and hospices are long term. Psychiatric hospitals are usually long term. Some acute care hospitals have units to treat acute psychiatric illness. Hospitals in the European Region now often serve both acute and chronic patients, but these two categories need to be better differentiated in order to optimize the use of resources and staff expertise (6).

Day care hospitals provide stay and treatment of patients during the day-time in the premises of the hospital, not including accommodation for lodging. Day care hospital is an important novelty in the hospital treatment, which has positive social, psychological and economical implications, if its work is adequately organized (4,6,12).

Types of service denote whether the hospital is „general" or „special". General hospitals provide a broad range of medical and surgical care, to which are usually added the specialties of obstetrics and gynecology; rehabilitation; orthopedics; and eye, ear, nose, and throat services. „General" can describe both acute and chronic care hospitals, but usually applies to short-term hospitals. „Special" hospitals offer services in one medical or surgical specialty (e.g., pediatrics, obstetrics/gynecology, rehabilitation medicine, or geriatrics) or treatment to certain diseases or groups of diseases (TBC, psychiatric diseases, heart and lung diseases etc.). Although special hospitals are usually acute, they

may also be chronic. A tuberculosis hospital is an example of the latter. University hospital as a special or specialized health institution for the education and training of health manpower with secondary and advanced training in health with university degrees in medicine, medical research and specialist treatment of in-patients (4,10).

A third classification divides hospitals by *type of control or ownership*: for profit (investor owned), or not for profit, governmental (federal, state, local, or hospital authority), religious or voluntary organizations.

Functions of the hospitals

The basic function of acute care hospitals is to diagnose and treat the sick and injured. The nature and severity of a patient's illness determine the care received and, to some extent, the type of hospital in which it is provided. Care might be delivered on an in-patient or out-patient basis. All acute care hospitals treat the sick and injured. Their emphasis on the other functions noted here depends on organizational objectives (5).

A second function is preventing illness and promoting health. Examples are instructing patients about self-care after discharge, referring them to other community services such as home health services, conducting disease screening, and holding childbirth and smoking cessation classes. The competitive environment has caused hospitals to mix illness prevention and health promotion with generous amounts of marketing.

A third function is educating health services workers. Physician education in residencies and fellowships is common. Acute care hospitals train staff such as nurse aid who will work in them. Acute care hospitals are a setting for many different types of health services workers who need clinical experience to receive a state license or professional society certification. Many health services management education programs require a residency, and it is common for managers to have spent time in an acute care hospital as an administrative resident or fellow. Clinic is a health organization that performs educational activities, professional training of health workers and scientific-research activity. The clinic performs the most complex types of health care from a certain medical branch that is from dentistry, creates and carries out professional and medical doctrinaire criteria from their field and offers professionally-methodological help to the health organizations from the related medical branch or dentistry.

A fourth function is research. Clinical trials for new drugs and devices come to mind first, but are the least common. Research such as assessing uti-

lization of intensive care units and determining why staff ignores universal precautions when treating emergency room patients are more common. One type of non-clinical research focuses on improving hospital processes through quality improvement. This could include using patient satisfaction surveys, increasing efficiency in patient billing, and improving ways to deliver supplies to nursing units.

Three generations of health care system reforms

Health care systems are continuously evolving. Impetus for reform of a health system may derive from a need for cost restraint, universal coverage, or efficiency in use of resources, or an effort to improve satisfaction of consumers or providers. The objective of improving the health of the population is also a motive, but this is often expressed as improved access, equity, efficiency, quality of care, and outcomes (7).

During the 20th century, there have been three overlapping generations of health system reforms. They have been prompted not only by perceived failures in health but also by a quest for greater efficiency, fairness and responsiveness to the expectations of the people that systems serve.

The first generation of reforms saw the founding of national health care systems, and the extension to middle income nations of social insurance systems, mostly in the 1940s and 1950s in richer countries and somewhat later in poorer countries. By the late 1960s, many of the systems founded a decade or two earlier were under great stress. Costs were rising, especially as the volume and intensity of hospital-based care increased in developed and developing countries alike. Among systems that were nominally universal in coverage, health services still were used more heavily by the better-off, and efforts to reach the poor were often incomplete. Too many people continued to depend on their own resources to pay for health, and could often get only ineffective or poor quality care (2).

These problems were apparent, and increasingly acute, in poorer countries. In low-income countries, the health system had therefore never been able to deliver even the most basic services to people in rural areas. Health facilities and clinics had been built, but primarily in urban areas. In most developing countries, major urban hospitals received around two-thirds of all government health budgets, despite serving just 10% to 20% of the population. Studies of what hospitals actually did revealed that half or more of all inpatient spending went towards treating conditions that could often have been managed by ambulatory care, such as diarrhea, malaria, tuberculosis and acute respira-

tory infections. There was, therefore, a need for radical change that would make systems more cost-efficient, equitable, and accessible.

A second generation of reforms thus saw the promotion of primary health care as a route to achieving affordable universal coverage. There was a very strong commitment to assuring a minimum level for all of health services, food and education, along with an adequate supply of safe water and basic sanitation. These were the key elements along with an emphasis on public health measures relative to clinical care, prevention relative to cure, essential drugs, and education of the public by community health workers. By adopting primary health care as the strategy for achieving the goal of „Health for All" at the Joint WHO/UNICEF International Conference on Primary Health Care held at Alma Ata (now Almaty, Kazakhstan) in 1978, WHO reinvigorated efforts to bring basic health care to people everywhere. The main aspects of the reorientation of primary health care related to the new focus - from illness to health and from care to prevention; to the new content - from treatment to health promotion and from episodic care to continuous care; to the new organization - from specialist to general practitioner and from physician to nurse; and to the new responsibilities - from passive reception to self-responsibility and from professional dominance to community participation (2,17).

The term „primary" quickly acquired a variety of connotations, some of them technical (referring to the first contact with the health system, or the first level of care, or simple treatments that could be delivered by relatively untrained providers, or interventions acting on primary causes of disease) and some political (depending on multi-sectoral action or community involvement). The multiplicity of meanings and their often contradictory implications for policy help explain why there is no one model of primary care, and why it has been difficult to follow the successful examples of the countries or states that provided the first evidence that a substantial improvement in health could be achieved at affordable cost. There was a substantial effort in many developing countries to train and use community health workers who could deliver basic, cost-effective services in simple rural facilities to populations that previously had little or no access to modern care and by placing major emphasis on the economic benefits of prevention and cost-effective measures to reduce the burden of disease (2,7,9,19).

Despite these efforts, many such programs were eventually considered at least partial failures. Funding was inadequate; the workers had little time to spend on prevention and community outreach; their training and equipment were insufficient for the problems they confronted; and quality of care was often so poor as to be characterized as „primitive" rather than „primary", par-

ticularly when primary care was limited to the poor and to only the simplest services. Referral systems, which are unique to health services and necessary to their proper performance, have proved particularly difficult to operate adequately. Lower level services were often poorly utilized, and patients who could do so commonly bypassed the lower levels of the system to go directly to hospitals. Partly in consequence, countries continued to invest in tertiary, urban-based centers.

In developed countries, primary care has been better integrated into the whole system, perhaps because it has been more associated with general and family medical practice, and with lower-level providers such as nurse practitioners, and physician assistants. Greater reliance on such practitioners forms the core of many developed countries' current reform agendas. Managed care, for example, revolves to a large extent around the strengthening of primary care and the avoidance of unnecessary treatment, especially hospitalization (2,9).

The approach emphasized in the primary health care movement can be criticized for giving too little attention to people's demand for health care, which is greatly influenced by perceived quality and responsiveness, and instead concentrating almost exclusively on their presumed needs. Systems fail when these two concepts do not match, because then the supply of services offered cannot possibly align with both. The inadequate attention to demand is reflected in the complete omission of private finance and provision of care from the Alma Ata declaration, except insofar as community participation is construed to include small-scale private financing (2).

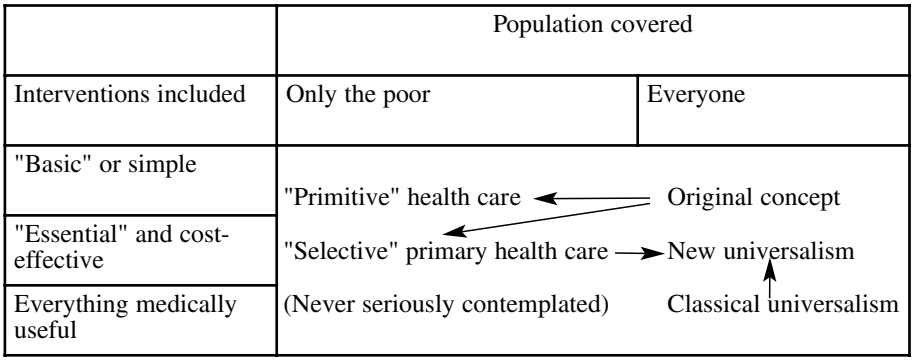
Universal access to health care does not necessarily address social inequalities in health. Removal of financial barriers by itself does not guarantee good health. Many social, cultural, and environmental health risk factors are not correctable or preventable by medical or hospital care. They may be of greater importance than the medical care provided. It is therefore useful to understand how the models for reform evolved, their successes and failures, and how they are continuing to develop (7).

Poverty is one reason why needs may not be expresses in demand, and that can be resolved by offering care at low enough cost, not only in money but also in time and non-medical expenses. But there are many other reasons for mismatches between what people need and what they want, and simply providing medical facilities and offering services may do nothing to resolve them. In general, both the first-generation and second-generation reforms have been quite supply-oriented. Concern with demand is more characteristic of changes

in the third generation currently under way in many countries, which include such reforms as trying to make „money follow the patient" and shifting away from simply giving providers budgets, which in turn are often determined by supposed needs (2,3).

If the organizational basis and the quality of primary health care often failed to live up to their potential, much of the technical footing remains sound and has undergone continuous refinement. This development can be sketched as a gradual convergence towards what WHO calls the „new universalism" – high quality delivery of essential care, defined mostly by the criterion of cost-effectiveness, for everyone, rather than all possible care for the whole population or only the simplest and most basic care for the poor (see Figure 2).

Figure 2. Coverage of population and of interventions under different notions of primary health care (2)



There were common notions that health and nutrition interventions can make a substantial difference to the health of large populations and of obtaining „good health at low cost" by selectively concentrating efforts against diseases that account for large, avoidable burdens of ill-health. That was the basis for a set of core public health interventions and a package of essential clinical services influenced by PHC models, variously called „basic" or „essential" or „priority" that have been recommended by the World Bank and developed in several countries, in the 1990s, from epidemiological information and estimates of cost-effectiveness of interventions. And the common failures in diagnosis and treatment due to inadequate training and excessive separation among disease control efforts have led to the development of clusters of interventions and more through training to support their delivery, most notably in the integrated management of childhood illness (2,9,19).

This evolution also implies an emphasis on public or publicly guaranteed and regulated finance, but not necessarily on public delivery of services.

And it implies explicit choice of priorities among interventions, respecting the ethical principle that it may be necessary and efficient to ration services but that it is inadmissible to exclude whole groups of the population. However, it is easier to define a set of interventions that would preferentially benefit the poor if fully applied to the population, than it is to assure either that most of the poor actually do benefit, or that most of the beneficiaries are poor. Government health care services, although usually intended to reach the poor, often are used more by rich.

Despite the health reforms of recent decades, inadequate progress has been made in building health systems that promote collective health improvement. The 1990s was a decade of major reforms in national health systems. All countries are struggling to develop adequate prevention models to reduce the burden of disease that can bankrupt a national health system. The ideas of responding more to demand, trying harder to assure access for the poor, and emphasizing financing, including subsides, rather than just provision within the public sector, are embodied in many of the *current third-generation reforms*. These efforts are more difficult to characterize than earlier reforms, because they arise for a greater variety of reasons and include more experimentation in approach. In part, they reflect the profound political and economic changes that have been taking place in the world. By the late 1980s, the transformation from communist to market-oriented economies was under way in China, Central and South East Europe, and the former Soviet Union (2,7).

Health systems have not been immune from these large-scale changes. One consequence has been a greatly increased interest in explicit insurance mechanisms, including privately financed insurance. In developed countries, which already had essentially universal coverage, usually less drastic changes have taken place in how health care is financed. But there have been substantial changes in who determines how resources are used, and in the arrangements by which funds are pooled and paid to providers. General practitioners and primary care physicians, as „gatekeepers" to the health system, have sometimes been made accountable not only for their patients' health but also for the wider resource implications of any treatments prescribed. In some countries this role has been formalized through establishing „budget holding" for general practitioners and primary care physicians, for example, through general practice „fund holding" in the UK, Health Maintenance Organizations in the USA, and Independent Practice Associations in New Zealand. And in the United States, there has been a great shift of power from providers to insurers, who now largely control the access of doctors and patients to one another.

In the European Region, in recent years, many health care reforms

have taken place. Many governments started to introduce various market mechanisms into service delivery by purchaser/provider split, introduction of competitive elements into health services, and various payment mechanisms. The Ljubljana Charter, adopted by all Member States in 1996, emphasized that health care reforms should be an integral part of an overall health policy and that health care systems need to:

- Be governed by the principles of human dignity, equity, solidarity and professional ethics;
- Relate to clear targets for health gain;
- Address citizens' needs;
- Aim at continuous improvements in the quality of care;
- Ensure financing that will enable health care to be provided to all citizens in a sustainable way; and
- Be oriented towards primary health care.

It means that the reform of health care provision and its financing should be comprehensive in order to safeguard the development of adequate and affordable health care services. For example, reforms in the organizational structure of the health system should be accompanied by legislative adaptations, or reforms in secondary and primary care provision should be accompanied by reform in the health financing system.

In CSEE countries, after the breakdown of the state socialism, a number of changes have occurred in the legal framework, as well as governmental policy, ownership, production, financing and reimbursement of health care providers. Priority setting was necessary step to ensure the efficient use of insufficient public funds for health. Because of shortage of funds many cost-effective interventions were neglected, under funded or provided with low quality standards. It was necessary in these countries the priority setting in health care to be driven by new democratic values and the new systems to be people-centered and more oriented to the needs of individual patient and specific groups, and sensitive to inequalities, unemployment, and social poverty. Health systems also should be health-focused and evidence based, and oriented towards primary health care (20).

Despite the structural diversity and underlying philosophical differences in national health systems, there are important common elements. They are large employers and among the largest industries in their respective countries. All face problems of financing, cost constraint, overcoming structural

inefficiencies, and, at the same time, finding incentives for high quality and efficiency (7).

In the years ahead health systems will face new challenges, because of the aging of the population, medical technology innovations, and high professional and public expectations, and new pressures to constrain costs and resolute commitment to the primary health care values of equity, universal access to care, community involvement and intersectoral action. Those principles will be more important than ever. Still, much remains to be understood about how health systems function, why they fail or respond slowly to some crises, and about how primary health care principles can be translated into practice policies that will yield health improvements for communities (1).

EXERCISE: The Role and Organization of Health Care System

Task: Students should visit www.observatory.dk to become familiar with different Health Care Systems and actual reforms initiatives. Students are encouraged to write draft describing HCS in their respective country, using Production template questionnaire, which is available on site given above.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Health Care System of the Federation of Bosnia and Herzegovina**
Module: 1.2	**ECTS (suggested): 0.25**
Author(s), degrees, institution(s)	Dr Enida Imamovic, Specialist of Social Medicine, Public Health Institute of Federation of B&H; Dragana Niksic, MD, PhD, Ass. Professor of Social Medicine, Medical Faculty, University of Sarajevo
Address for Correspondence	Enida Imamovic, Public Health Institute of FB&H, Titova 9 71000 Sarajevo Bosnia and Herzegovina Tel: +387 33 20 88 13 Fax: +387 33 22 05 48 E-mail: imamovic@bih.net.ba
Keywords	Organization, health care system, reform, indicators
Learning objectives	At the end of this module - case study, students would become familiar with the organization of the health care system and health care reform process of the Federation of Bosnia and Herzegovina.
Abstract	According to the B&H Constitution, health care regulation and competence are transferred to the entity level. Federation B&H consists of ten cantons, health care system is decentralized. The transition of the health care system has started in early 1990s and it has been continued after the war ended in 1995. The main aim of the health care system reform in FB&H is to rationalise health care on the basis of PHC strengthening. In line with the Law, there are three levels of health care: primary care level, specialists or consultant's level, and tertiary care level. Within primary health care (PHC), family medicine teams are implemented. On this level are also implemented community mental health centres and physical rehabilitation centres. Strengthening of PHC is accompanied by rationalisation of hospital care. Hospital care capacities have been decreasing, as outlined in the Reform documents. Although the use of capacities has slightly grown it is still under standard occupancy, which means that capacities are insufficiently used. The package of patient's rights is not defined yet.
Teaching methods	After an introduction lecture students will work in small groups on recognizing strengths and weaknesses of the health care system and health care reform process of the Federation of Bosnia and Herzegovina, which will be followed by group reports and overall discussion.
Specific recommendations for teacher	This module to be organized within 0.25 ECTS credit. Beside supervised work, students should be informed about WHO indicators and specific indicators for their country regarding health care organization in order to describe main principles/problems respective to their country.
Assessment of Students	Practical work: Health Care System in line with WHO Indicators (in students' countries), Improvement in Health Care System proposal/reform proposal (papers and discussions).

HEALTH CARE SYSTEM OF THE FEDERATION OF BOSNIA AND HERZEGOVINA

Enida Imamović, Dragana Nikšić

Introduction

As a republic of former Yugoslavia, Bosnia and Herzegovina had a health system financed by „self-managed" communities, which ran health insurance, social security and disability insurance for employees and their families at the municipal level. From 1991, at the federal level, risk pooling took place through a republic-wide, compulsory health insurance scheme, administered by a central insurance fund. During the war from 1992-95 health financing was organized directly by the republic's then Ministry of Health, while the health insurance fund practically ceased to operate. Provision of elective health care was reduced to a minimum, and a number of new provider units were established for emergency care. However, it is estimated that about 30% of health care facilities were destroyed or heavily damaged during the war (1).

Dayton Peace Agreement of 1995 has divided Bosnia and Herzegovina (B&H) in two entities: Federation B&H and Republic of Srpska. According to the B&H Constitution health care regulation and competence are transferred to the entity level. Within Federation B&H, health care competence is divided between Federal and cantonal authorities which resulted with decentralisation of health care while coordination role is attributed mainly to the federal level. A third health system was created in 2000 in the district of Brčko, as an administrative unit under the federal sovereignty of B&H and international supervision that covers an estimated 90,000 population. In addition to Republic Srpska and District of Brčko, Federation of B&H consists of ten cantons and each of them has its own Government and Assembly. The cantons involve 79 municipalities, which are basic social and political communities.

Method

This outline is focused on the representation of FB&H health care system resources in 2002 in line with WHO indicators. The outline is based on data available from official statistics.

For comparative survey are chosen countries in transition which by health related factors are the most matching the Federation B&H (Albania, Bulgaria, Croatia, Macedonia, Romania, CEE - Central and East European Countries).

Demographic indicators

Federation of Bosnia and Herzegovina covers 25 989 km^2, which is about 51% of the whole B&H territory. In 2002, on the territory of the Federation lived 2 315 270 inhabitants.

According to the data of Federal Ministry of Displaced People and Refugees, in the Federation B&H in 2002 lived 199 093 displaced persons or 8.6%. The average density of the population is 89 persons per square kilometre. The regional diversity is evident.

The persons over 65 years make 11% of the total population, while the age group 0-14 years makes 20.6%, so that the population of FB&H may be classified as stationary regressive by its biological type.

Socioeconomic indicators

In 2001, GDP per capita was 1,176 US$ (2). Average monthly pay in 2002 was 279,3 US$ or 482,71 BAM (on 14.07.2003, 1 US$ mean value was 1,7285 BAM).

The working age population makes 57.40% of the total population. In 2002, the percent of unemployed reached 42.45% and was increased related to the previous years (1998, it was 39.34%).

According to the estimations, in 2002, the general socio-economic situation is very complex as 10% of total population are persons with different levels of disability, and 3.9% of population is on social benefits, out of which 14.1% are children.

Health care system reform

The transition of the health care system has started in early 1990s. The war in 1992 ceased the reform process but it has been continued in 1995. The Law on health care (3) and the Law on health insurance (4), both adopted in 1997, support the reform. In 2002, the health care standards and norms for obligatory health insurance were adopted.

Some of the reasons that incited the reform are new socio-political and socioeconomic changes; still existent war implications in health care resources, increase of health care demands, etc.

The main aim of the health care system reform in FB&H is to ensure more rational health care on the basis of primary health care (PHC) strength-

ening as outlined in the Reform documents (5) and in Health for all in the 21st century (6).

Within PHC, family medicine teams are implemented. Also, on this level are implemented community mental health centres and physical rehabilitation centres.

Strengthening of PHC is accompanied by rationalisation of hospital care.

The social, political and economic changes in the society were followed by the process of health care sector privatization.

In addition, it should be stressed that premises and equipment in health sector is partly destroyed, damaged, or obsolete and that slow down the reform trends (7).

Health system organization

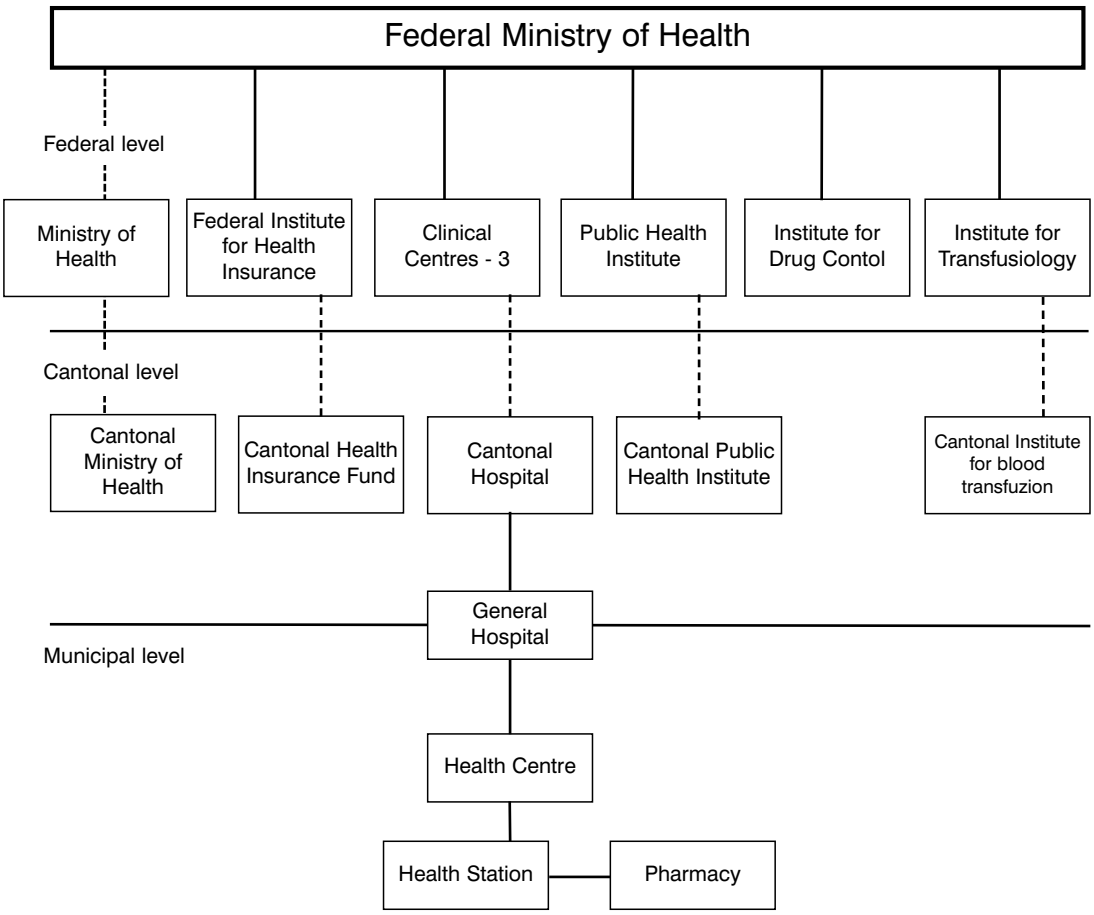
In accordance with the Law (3), there are three levels of health care: primary care level, specialists or consultant's level, and tertiary care level (Scheme 1).

Municipality level includes: health centres with health services in community and pharmacies.

Cantonal level includes: ministry of health, general hospital, cantonal hospital, special hospitals, institute for blood transfusion, public health institute and health insurance fund.

Federal level includes: ministry of health, clinical centres, institute for blood transfusion, public health institute, institute for drug control, and health insurance fund.

Scheme 1. Health System Organization in the FB&H

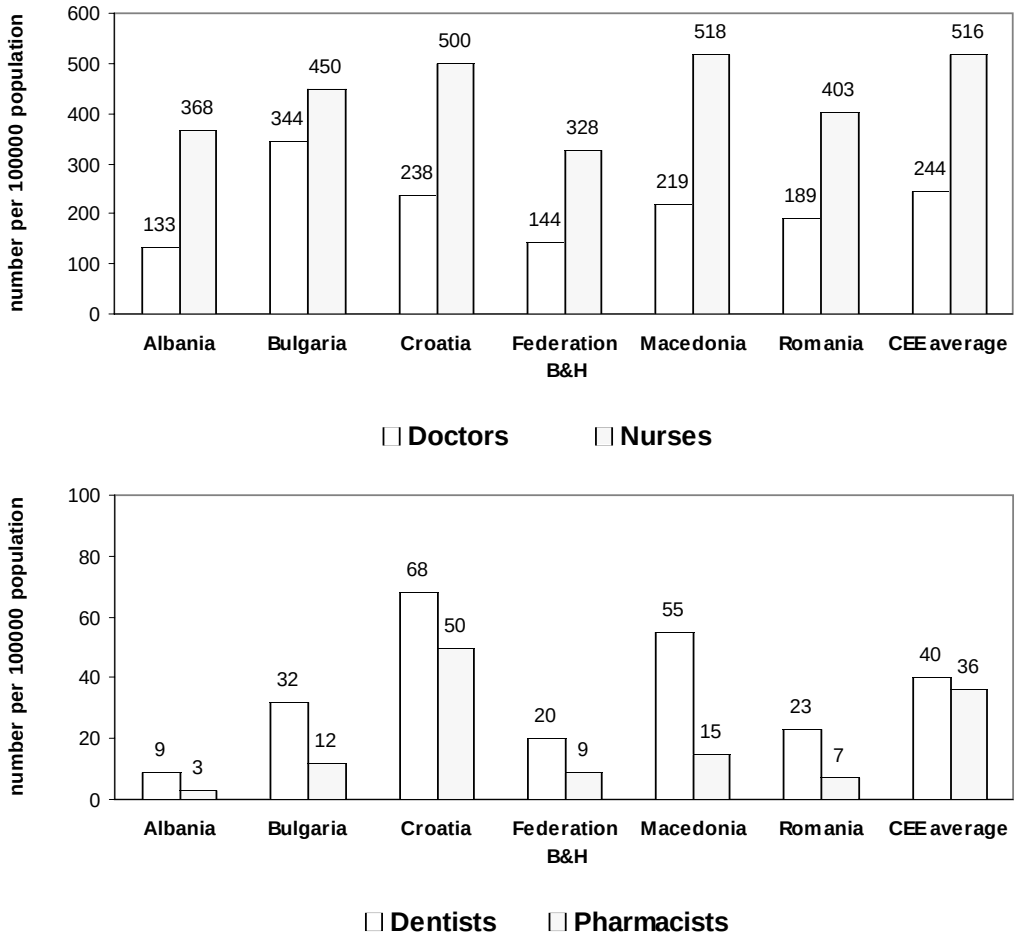


Source: Strategic health system plan, the Federation of B&H, July 1998

Survey of health professionals in FB&H in comparison with some countries in transition

The comparative survey of health care professionals shows that, by number of doctors in 2002 (144 doctors per 100000 people) and by the number of nurses FB&H is on the bottom. Only Albania has even smaller number of dentists per 100000 populations; Albania and Romania are behind FB&H by the number of pharmacists (8,9).

Figure 1. Health professionals per 100000 population in some countries in transition (data for year 2002)



Source: WHO Regional Office for Europe Health for All database 2002, 2003 and Public Health Institute of Federation of B&H (data for Federation B&H)

Primary health care

The institutions that provide primary health care are Health Centers (Dom zdravlja). Medical services delivered by Health Centers include: general practice, maternal and child health, school medicine, health care for specific and non-specific lung diseases, and dental care; they also ensure hygiene services (epidemiological activities), emergency medical aid, laboratory, radiology and other diagnostic services. Within the area of each health center, there is an outpatient service located in the district (10).

In line with the reform trends, the family medicine concept has been successively implemented. Within health care system, family medicine services are the places of the first contact with patient. At the same time, family medicine teams (one team consists of GP and nurse) carry out activities on prevention and treatment of the population, in line with the European definition of family medicine (WONCA). These teams are providing services for around 1,500-2,500 people. Family medicine teams should meet about 80% of demands for health care (3,5,11).

In Federation B&H, in the year 2002, primary health care was delivered within 872 units. There were 55 doctors and 120 nurses per 100000 populations.

Moreover, on this health care level, already exist community mental health centres and physical rehabilitation centres.

There were 20 dentists and 9 pharmacists per 100000 populations.

Table 1. Primary health care indicators in the FB&H in 2002

WHO indicators	Value
Units (number)	872
Physicians/100000	55
Dentists/100000	20
Pharmacists/100000	9
Nurses/100000	120

Source: Public Health Institute of Federation of B&H

Usually, PHC teams appropriately cover the population, but availability is not equal in terms of geographical regions.

Data related to the private health sector are not available.

Specialist's or consultant's health care

Health Centres have also organised units to deliver specialists or consultants services, if such services were not organised within other health institutions (10). During the year 2002, this type of health care was delivered in FB&H within 424 units involving 436 working teams. There were 19 doctors and 26 nurses per 100000 populations.

Table 2. Changes in Network and Manpower of the PHC and Consultants/ Specialists HC in FBH in the period 1998-2002

Network and Manpower	Levels of Health Care					
	Primary Health Care			Consultants/Specialist Health Care		
	2002	1998	Index 2002/1998	2002	1998	Index 2002/1998
Units	872	904	96.4	424	302	140.4
Doctor's offices	1194	1238	96.4	429	244	175.8
Doctors	1269	1364	93.0	436	315	138.4
Nurses	2776	3078	90.2	604	435	138.8

Source: Public Health Institute of Federation of B&H

Consultants/specialists health services are also provided in institutes for blood transfusion, occupational medicine, sport medicine and physical medicine and rehabilitation.

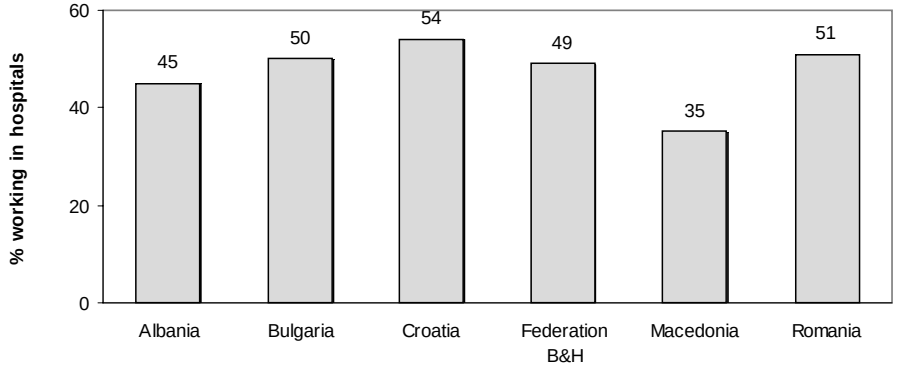
Although the health care policy of Federation B&H is oriented towards strengthening primary health care, the data related to the previous period demonstrates more extensive development of consultants/specialists care (12,13,14).

Hospital care

Secondary level, i.e. hospital care, includes services delivered within general, cantonal and special hospials and partly clinical centres. Tertiary care is provided within clinical centres (university hospitals).

Hospital care in the year 2000 involved 48.7 % of all medical doctors, and 55.4 % of nurses. Comparative survey shows that by percentage of physicians working in hospitals FB&H is somewhere in the middle.

Figure 2. Physicians working in hospitals (%) in some countries in transition in 2002



Source: WHO Regional Office for Europe Health for All database, 2003 and Public Health Institute of Federation of B&H (data for Federation B&H)

Significant decrease in hospital capacities occurred during the last years. Hospital bed rate per 100000 population was reduced from 400 beds in 1998 to 350 beds in 2002. There were 5.0 beds per one doctor, and 1.9 beds per one nurse, which is very high standard.

Table 3. Hospital care indicators in the FB&H in 2002

WHO indicators	Value
% Physicians working in hospitals	49
% Nurses working in hospitals	55
Number of hospital beds/100000	350
Bed occupancy rate	68,4%

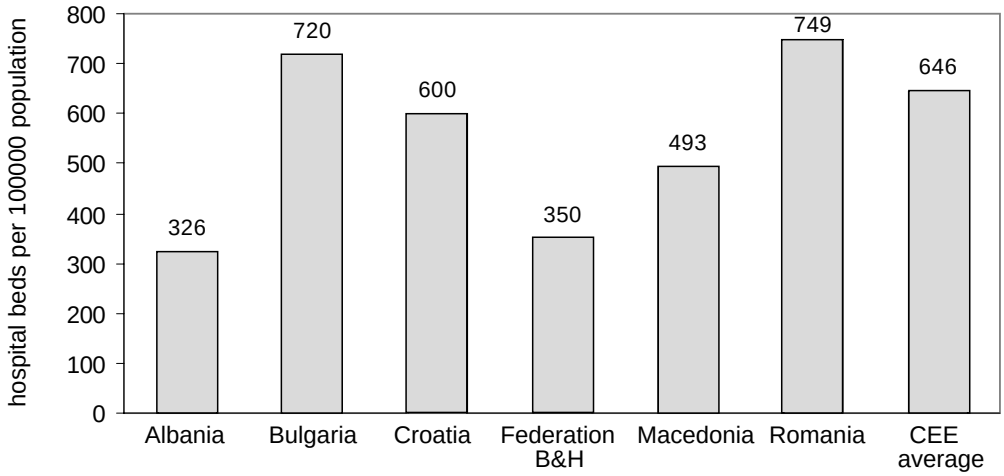
Source: Public Health Institute of Federation of B&H

The bed occupancy was 68.4%, which is still very low showing insufficient use of existing bed capacities.

The decrease in hospital beds was not followed by the decrease of number of doctors working in hospitals.

Compared with the countries in transition, Federation B&H, with 350 beds per 100000 population, left only Albania behind.

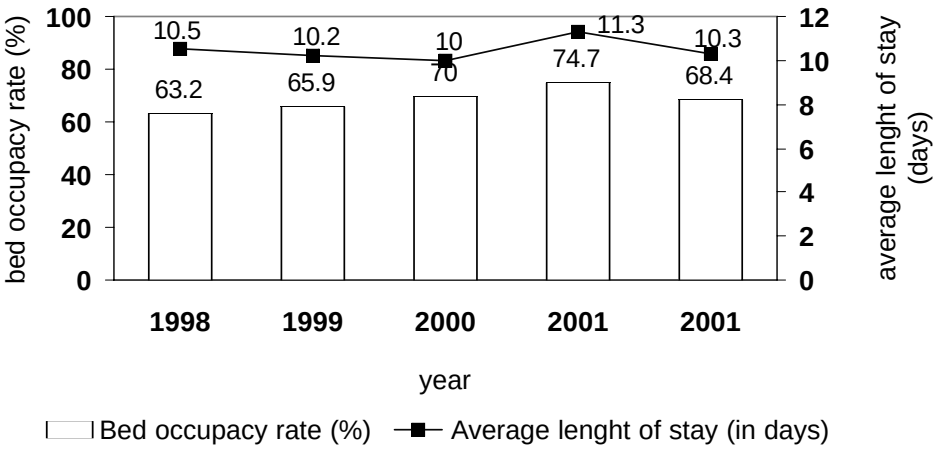
Figure 3. Hospital beds per 100000 population in some countries in transition in 2002



Source: WHO Regional Office for Europe Health for All database, 2003 and Public Health Institute of Federation of B&H (data for Federation B&H)

Average length of stay (in days) in 2002 was 10 days and did not indicate more significant changes in the observed period. In 2002, the beds occupancy was 68.4%, showing a decrease related to the two previous years, and demonstrating inadequate use of existing bed capacities.

Figure 4. Use of hospital resources in FB&H in the period 1998-2002



Source: Public Health Institute of Federation of B&H

Hospital care capacities have been decreasing, as outlined in the Reform documents, but the use of capacities was still under standard occupancy.

Funding

The Reform includes health care funding, also.

About 17% of gross wages (without deductions) go to the health care funds. Funds are raised and allocated at the cantonal level.

Recent legislation allows some transfer of resources across the cantons to be redistributed by the Federal Health Insurance Fund.

The establishment of the „Federal Solidarity Fund" in January 2002 aims at increased intercantonal cooperation to diminish inequities in access to health care by reducing duplication of services, enabling the movement of patients across locations to receive needed services where available, and potentially reducing the fragmentation of services between cantons. Moreover, lower income cantons will be able to benefit from expensive interventions. The fund is financed by contributions from cantonal health insurance funds (8% of their

overall income), and general revenues. The aim is to resolve the problem of lack of contributions by non-earners and to help to equalise health revenues across FB&H.

On the basis of the proposal of Federal Government, Federal Parliament adopts each year „the package of patient's rights". The aim is to establish a uniform, federation-wide package to ensure equal access. This „package", to be provided under compulsory social insurance is still under development (1,4).

Conclusions

1. Health care system in the Federation B&H is going through the process of transition. This process has started in early 1990s, before the war and it has been continued in 1995. Currently, the Reform is stipulated by democratic changes and market economy.
2. The Reform includes changes of legislation, foundation and management of health facilities, raise and distribution of financial resources, etc.
3. As a result of Dayton Peace Agreement, the health sector is decentralised; large rights are given to the cantons, while Federation is acting as a co-ordinator.
4. The process of privatisation has started in early 1990s although (many questions were still unsolved) with insufficient regulation.
5. Facilities and equipment are partly destroyed, damaged, or outdated slackening the Reform trends.
6. Health sector reform is based on strengthening of primary health care (PHC) and rationalisation of hospital care. In average, PHC teams appropriately cover the population, but availability is not equal. Family medicine teams, community mental health centres and physical rehabilitation centres are still in the phase of implementation.
7. During the reform period, hospital bed number was reduced although the occupancy is still low indicating the inadequate use of hospital capacities.
8. The package of patient's rights is not defined yet.
9. Comparative analysis of indicators of health care system showed that Federation B&H, related to other observed countries, is amongst the last ones. Moreover, the available data demonstrated inadequate use of the existing capacaties. Therefore, due to the shortage of comprehensive data

for both private and public sector, the targeted operational research is necessary for the identification of actual status of organization and use of resources.

EXERCISE: Health Care System of the Federation of Bosnia and Herzegovina

Task: After reading this case study under the supervision of lecturer, students are asked to split and work in small groups (4-6 students) in order to discuss and decide possible recommendations they would make for the improvement of health care system in Bosnia and Herzegovina, following conclusions which were given above.

Written recommendations will be presented to the whole group.

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Recommended Readings

- National Law on Health Care
- National Law on Health Insurance
- National standards and regulations.
- WHO: Health for all in the 21st century. WHO Regional Office for Europe Copenhagen, 1999
- WHO: Health for All - Statistical database. Regional Office for Europe. Copenhagen

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT **A Handbook for Teachers, Researchers and Health Professionals**	
Title	**Electronic Health Records - the Core of the National Health Information System**
Module: 1.3	**ECTS (suggested): 0.75**
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Keywords	Health information, Electronic health record (EHR), Information and communication technology (ICT), EHR context/building blocks
Learning objectives	After completing this module students and public health professionals should have: • increased their knowledge about the health information systems and accepted a basic of electronic health record (EHR); • learnt about electronic health record architecture, which represents the generic structural components upon all EHRs are built;· • understood principles underpinning the EHR; • learnt about necessary context blocks: Person Identifier, Facility Identifier, Provider Identifier, Health Information generated through health events in a form of event summaries and Administrative Information; • gained knowledge of necessary building blocks, such as privacy, confidentiality, and security; standards; telecommunication infrastructure and encouraging uptake and use of information and communication technology (ICT); • highlighted difficulties and risks associated with EHR development; • recognized the importance of EHR for the future development of (national) health information system, especially in countries in transition; and • increased their skills necessary to participate in the process of EHR development in their own countries.
Abstract	Modern information and communication technologies offer an opportunity to improve health information systems, reengineer and revitalise the processes and procedures currently in place. At the same time, modern health care is not provided by one institution or by one group of health care professionals alone. Hence, today it is considered that the keystone of a system for sharing data, information and knowledge between different partners in health system is the electronic health record (EHR). Through an interoperable EHR the sources of information available to all partners in health system, primary and secondary users, can be extended, expanded and harmonized. As such, the EHR should be the core of the new generation of health information systems. EHR, as longitudinal collection of personal health information and under the control of a known party by an agreed access policy, requires at least next components:

	Person Identifier, Facility Identifier, Provider Identifier, Health Information generated through health events in a form of event summaries and Administrative Information. The shared electronic health record model is one that essentially provides for the systematic collection (at point of care), transfer, storage and retrieval of basic health, demographic, prescription and administrative data in the form of event summaries to be presented with appropriate authorization, via meaningful views and reports. EHR systems provide mechanism for the communication of records or their parts through a network of electronic health records.
Teaching methods	Lecture, individual work, group work
Specific recommendations for teacher	This module should be organized within 0.75 ECTS, out of which one third will be under the supervision of teacher. After an introductory lecture the students should work individually to fill in the questionnaires, which have to explore their knowledge and attitudes towards time of different EHR data storage and the concept of data privacy and security. Students will analyse the questionnaires in small groups and discussed in plenary session. In addition teacher should be ready to help the students in searching the Internet to find different national examples of the EHR development.
Assessment of students	Multiple choice questionnaires, written report with comparison of different EHR development.

ELECTRONIC HEALTH RECORDS - THE CORE OF THE NATIONAL HEALTH INFORMATION SYSTEM

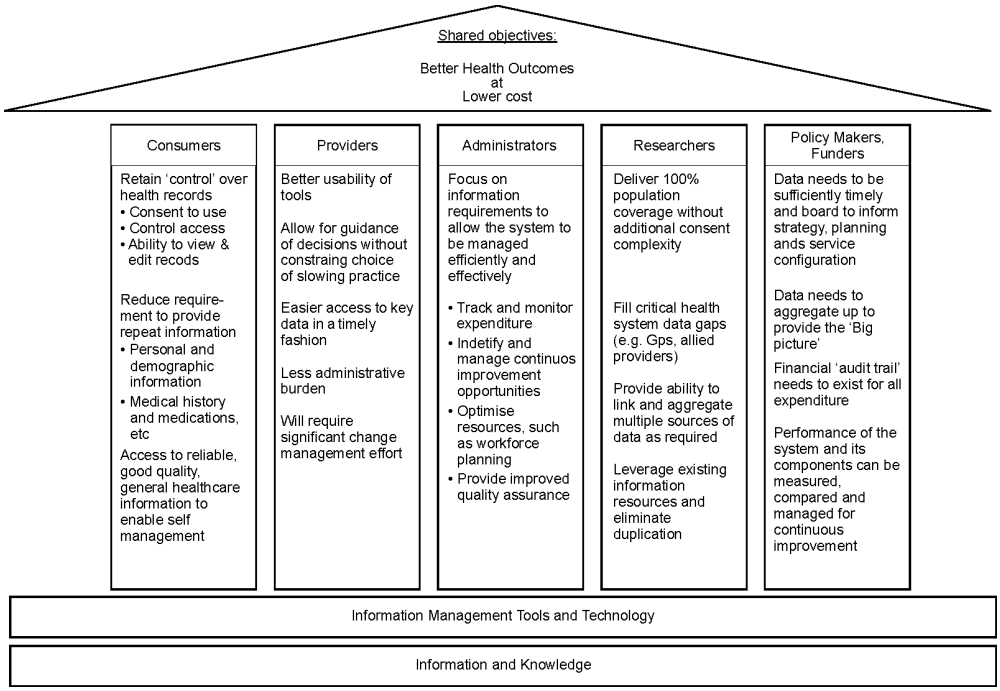
Jelena Marinković, Vesna Bjegović

The health sector is arguably one of the most information-dependent businesses of all in which information requirements can be classified, for example, as: information for citizens, patient education services, health management information, personal health data, decision support systems for health care professionals and life long learning for health care professionals.

The development of the national health information system is seen as one of the most important infrastructure prerequisite for initiating, implementing, monitoring, evaluating and targeting the changes within the health care reform. The support to the reform process is based on the development and improvement of management in the health care system, that is: creation of conditions for evidence-based decision making provided for health care providers, patients/citizens and health-care policy makers, and measurement of key dimensions of the health care system, that is: its availability, equity, quality, efficiency, financial and institutional sustainability (1).

There is widespread consensus that the underlying rationale for information management and information & communication technology (IM&ICT) - driven health reform is to improve health outcomes for citizens while containing health system costs. However, while sharing this overarching objective, different stakeholder groups are pursuing a range of different outcomes. Figure 1 shows the specific outcomes sought by five key stakeholder groups through the application of information management tools and technology as well as information and knowledge (2).

Figure 1. Stakeholder Objectives for IM&ICT

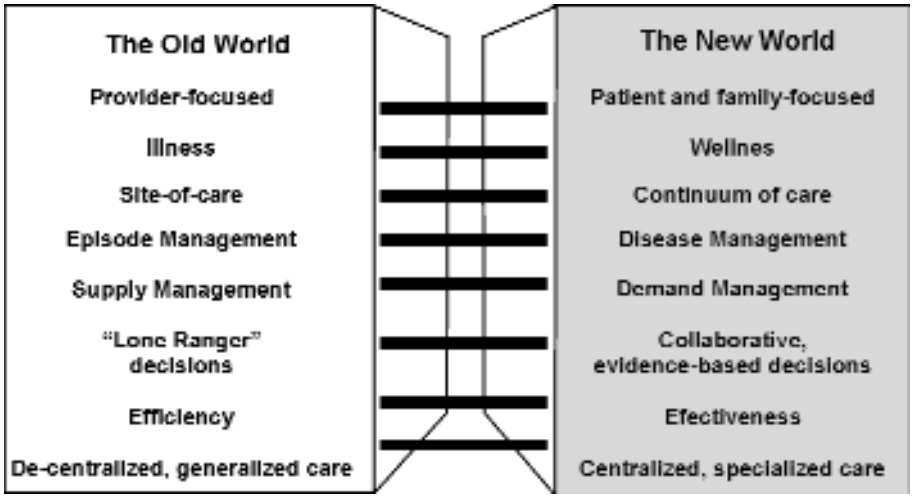


Source: The Boston Consulting Group, National Health Information Management and Information & Communications Technology Strategy, Australia 2004 (2)

Background

The fundamental changes are occurring in the health care sector worldwide. Economic, social and many other drivers are forcing changes to the focus of health care. As written and visually displayed in *Canada EHRS Blueprint*, first and foremost, health care is becoming a more patient-driven (Figure 2 (3)). Similarly, there is a demonstrated understanding of the need to shift the focus of health care efforts from the management of illness to the maintenance/promotion of wellness. As a result, we are seeing increased emphasis on the management of diseases across the continuum of care and along the lifecycle of the disease (3).

Figure 2. The Changing World of Healthcare (3)



Source: EHRS Blueprint Version 1.0 Page 15 © 2003 Canada Health Infoway Inc.

While many of these changes are driven by advances in technology, they also require a capability from the health infostructure - a capability that does not fully exist today. In the new world we require access to health information not only across different systems but across different jurisdictions and domain boundaries. We require the ability to view health information from all sources and to use the infostructure to initiate orders and referrals to a broader range of care and service providers than is currently available through traditional mechanisms. This happens by extending the capabilities to work within a framework of interoperability. Through an interoperable Electronic Health Record (EHR) we can extend, expand, and harmonize the sources of information available to clinicians in their work. Therefore, the EHR is a neccessary tool for providing person-centred and continuing health care safely and efficiently (3).

There is a growing consensus on the value of an EHR. Only to cite MEDIREC Lisbon Declaration where it is recommended that the Member States promote a framework for action within Europe to further develop common aspects of the EHRs based on the following:

„The EHR is the nucleus of the relationship between the patient, the health care delivery system and all its professionals. As such, the EHR should be the core of the new generation of Health Information Systems.

The main objective of the use of any EHR must be to improve quality

in care by having record and its associated information always available for the health care professionals when needed at point of care.

The use of EHR should lead to direct benefits for the professionals by making their work more efficient. This will arise from supporting the diagnostic process, enhancing accuracy and completeness, improving medical knowledge and disease management, and allowing better preventive care and patient handling.

Within health care systems, either European, national, regional or local level, the use of appropriate EHRs, will also contribute to adequate planning and resource management, facilitation of continuity of care, registration of health care interventions, improvement of epidemiological and morbidity information, and hence, a more cost-effective care process.

The European citizens shall by means of any EHR have: guaranteed right of access to the health care he is entitled for, right of access to his individual data and related services, and the effective protection of his rights of free circulations with respect to the confidentiality of his individual data.

Further actions and developments on EHR's should be based upon standards and consensus that ensure interoperability, and allow EHR's coming from different origins to be reliable, communicable, recognisable and comparable" (4).

Defining Electronic Health Record

The terms 'Computerised Patient Record' (CPR), 'Computer-Based Patient Record' (CPR), 'Electronic Medical Record' (EMR), 'Computerised Medical Record' (CMR), 'Electronic Health Care Record' (EHCR), 'Electronic Patient Record' (EPR) and 'Electronic Health Record' (EHR) are terms often used to describe similar concepts. It is important to clearly define how these terms should be used to avoid confusion.

The United States uses the term computer-based patient record or CPR and the Institute of Medicine defines it as „an electronic patient record that resides in a system specifically designed to support users through availability of complete and accurate data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids" (5).

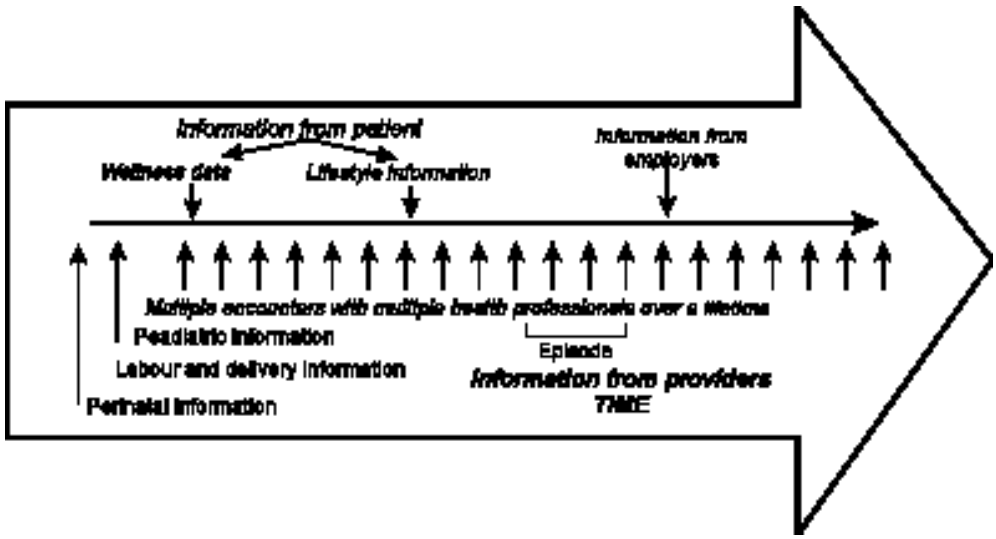
The United Kingdom has accepted two kinds of electronic records in health care - the electronic patient record (EPR) and the electronic health record (EHR) (6). Electronic Patient Record (EPR) describes the record of the

periodic care provided mainly by one institution. Typically this will relate to the health care provided to a patient by an acute hospital. EPRs may also be held by other health care providers. Thus, EPRs are considered proprietary and it is usual for EPRs not to be able to be transferred even to another site using the same EPR system. Electronic Health Record (EHR) is used to describe the concept of a longitudinal record of patient's health and health care - from cradle to grave, Figure 3. It combines both the information about patient contacts with primary health care as well as subsets of information associated with the outcomes of periodic care held in the EPRs.

For the purposes of this text we shall consider the Electronic Health Record to be - an electronic longitudinal collection of personal health information, usually based on the individual or family, entered or accepted by health care professionals which can be distributed over a number of sites or aggregated at a particular source including a hand-held device. The information is organised primarily to support continuing, efficient and quality health care. The record is under the control of a known party.

In certain circumstances, and with agreement of the appropriate professional and patient representative bodies, information from records held by social care organisations may also contribute to the EHR. In theory the EHR is therefore a combination of the bulk of the primary care EPR for a patient together with linking information from other record systems for that patient.

Figure 3. The Electronic Health Record after Murphy et al, 1999 (7)



Source: Heard et al (2000). The benefits and difficulties of introducing a national approach to electronic health records in Australia. Commonwealth Department of Health and Aged Care, Australia (8).

The Electronic Health Record (EHR) is an unusual concept - it is a record, a set of data - but it is not accessible without a computer system to interpret it. *EHR systems* provide the mechanism for the communication that records from part, a feature which differentiates such systems from stand-alone medical record systems. EHR systems operate in a defined technical environment with organised and interoperable components enabling management of and efficient access to information by qualified users via a graphical and potentially interactive multimedia user interface. Having launched an EHR within a system, the data within the EHR can at once be manipulated, viewed in different ways and processed into information which assists in the provision of health care. EHR systems also ensure security of the record and the confidentiality of personal health information.

Precisely, an *EHR system* is a combination of people, organizational entities, business processes, systems, technology and standards that interact and exchange clinical data to provide high quality and effective healthcare. It is made up of: mechanisms to find and uniquely identify people, providers and locations; patient-centric Electronic Health Records (EHR); presentation solutions and intelligent agents; common services and standards to enable integration and interoperability; workflow and case management; decision support services; services to support health surveillance and research; services to ensure privacy and security; and physical infrastructure to support reliable and highly available electronic communications across defined territory.

EHR Architecture (EHRA) represents the generic structural components from which all EHRs are built, defined in terms of an information model; i.e., it is a model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care, and may retain integrity across systems, countries, and time, independent of the technology used to implement the EHR system (9). An open standardised EHRA is the key to interoperability at the information level.

The framework used for the EHRA requirements comprises: structure (record organization, data organization, type and form of data, supporting health concept representation), process (clinical processes, record processes), communication (messaging and record exchange), privacy and security (privacy and confidentiality, consent, access control, data integrity, auditability of access), medico-legal aspects (support for legal requirements, actors), ethical aspects (support for ethical justification), consumer/cultural aspects (consumer issues, cultural issues) and evolution (support for EHRA and EHR system evolution) (10).

An *EHR Infostructure* (EHRI) is a collection of common and reusable components in the support of a diverse set of health information management applications. It consists of software solutions, data definitions and messaging standards for the EHR (3). It is made up of:

- Registry systems to manage and provide peripheral information required to uniquely identify the actors in the EHR. Specifically, these are the patient/person, the provider of care, and the location of care. Registries which hold patient/person consent information are part of the EHRi as well.
- Domain repositories that manage and persist subsets of clinical data that pertain to the EHR domain. A PACS system is an example of a Domain Repository.
- An EHR system to manage and persist person-centric clinical information.
- Standardized common services and communication services to sustain the interoperability of the different components within the infostructure, as well as to sustain the interoperability between infostructures and with feeder or application systems.
- Standardized information and message structures as well as business transactions to support the storage and exchange of information in and out of the EHR.

The Health Information Access Layer (HIAL) is an interface specification for the EHR Infostructure that defines service components, service roles, information models and messaging standards required for the exchange of EHR Data and the execution of interoperability profiles between EHR Services (3). The HIAL is broken down into two layers of services: the common services and the communication bus services. The common services layer is an aggregation of services that accomplish generic functions potentially reusable for any Registry, Domain Repository or EHR system available in a given EHRi. The communication bus services layer is an aggregation of services that pertain specifically to enabling communication capabilities in a peer-to-peer, highly distributed network of EHRi systems. This layer handles the receiving and sending of messages between any two systems in an EHRS.

The standard of the EHR is technology neutral. This means that the EHR can be printed out and transported by a patient or other authorized person, sent as a standard HL7 message, or sent as an XML message to be integrated into the patient information system.

Purpose of the EHR according to ISO/TS 18308 (10) - Primary purpose

of the EHR is to provide a documented record of care which supports present and future care by the same or other clinicians. The primary beneficiaries are the patient/consumer and the clinician(s). Any other purpose for which the record is used is considered secondary, as is any other beneficiary. The secondary uses are: medico-legal (evidence of care provided, indication of compliance with legislation, reflection of the competence of clinicians), quality management (continuous quality improvement studies, utilisation review, performance monitoring, benchmarking, accreditation), education (of students of the health professions, patients/consumers, and providers), research (development and evaluation of new diagnostic modalities, disease prevention measures and treatments, epidemiological studies, population health analysis), public and population health, policy development (health statistics analysis, trend analysis, case mix analysis), health service management (resource allocation and management, cost management, reports and publications, marketing strategies, enterprise risk management), bulling/finance/reimbursement (insurers, government agencies, funding bodies).

Principles underpinning the EHR, as defined by ISO/TS 18303 (10), are :

- The EHR should be timely, reliable, complete, accurate, secure and accessible and designed to support the delivery of healthcare services regardless of the model of healthcare being applied. It should interoperate in a way which is truly global yet respects local customs, language and culture.
- The EHR should not be considered applicable only to patients, individuals with the presence of some pathological condition. Rather, the focus should be on individual's health, encompassing both well-being and morbidity.
- The EHR recognises that an individual's health data will be distributed over different systems, and in different locations around the world. To achieve the integration of data, the EHR will require the adoption of a common information model by compliant systems and the adoption of relevant international standards wherever possible.
- To permit the development of meaningful EHR standards, boundaries must exist to define what is and is not regarded as part of the EHR at the time of standardization.

Characteristics of the EHR are according to Beale et al, 2002 (11):

- The EHR is *patient/consumer-centred*, and ideally includes information relevant to all kinds of carers, including allied health, and emergency services as well as patients themselves.

- The EHR contains observations (what occurred), opinions (decisions about what should occur), and care plans (plans for what should occur).
- The level of abstraction of the EHR is generalist, that is to say, specialised information such as images, guidelines or decision support algorithms are not typically part of the EHR per se; rather interfaces exist to standards for other, specialized systems.
- The EHR is a sink of diagnostic and other test data.
- The EHR is a source of clinical information for human carers, decision support, research purpose, governments, statistical bureaux, and other entities.
- The EHR is a long term accumulator of information about what has happened to or for the patient.

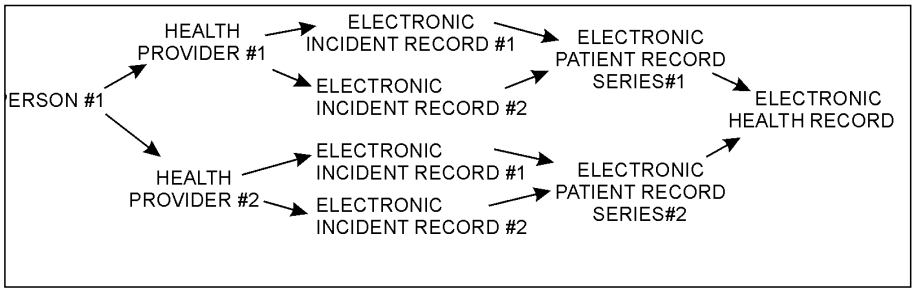
Therefore EHR is not:

- An alternative for the detailed information concerning all diagnostic and treatment information held in local clinical systems;
- The source of decision support, although it supports and extends the value of decision support systems, or
- A full copy of all patient records in electronic form.

Building Electronic Health Records

An overview of EHR building path comes out from an excellent report done by Office of Technology and Information Highway Canada. Figure 4 illustrates the sequence of building the EHR. Diagram depicts an oversimplified view of the EHR. To gain a more accurate appreciation of its complexity and breadth of information, one must recognize the wide range of health information sources. Each time an individual visits a health care provider, data are generated.

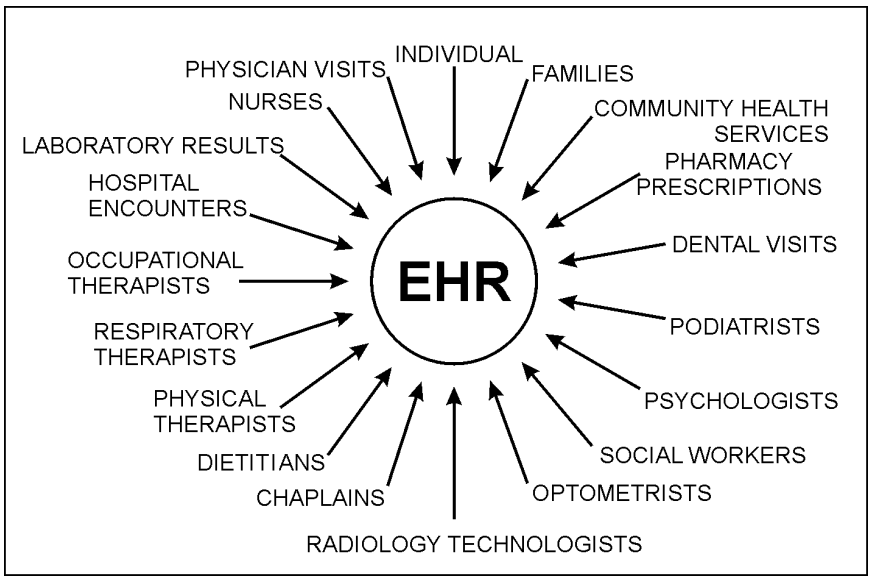
Figure 4. Creation of an electronic health record



Source: Toward Electronic Health Records. Office of Technology and Information Highway Canada, 2001 (13).

The following diagram, Figure 5, identifies some of the sources of data for an EHR as listed by the USA Institute of Medicine (Committee on Data Standards for Patient Safety, 2003) (12).

Figure 5. Sources of health related data

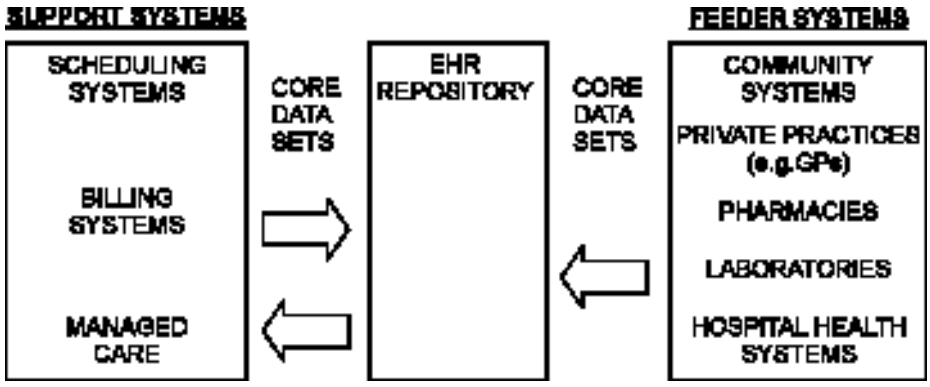


Source: Toward Electronic Health Records. Office of Technology and Information Highway Canada, 2001 (13).

Once the data have been collected, they are placed in many repositories or databases that are part of many health systems. From these systems, specific pieces of a patient's information are combined to create a core data set that is made available to other systems. The core data set includes health and administrative data. Its format must be agreed to by all stakeholders. The sys-

tems providing the information are referred to as feeder systems (e.g. laboratory systems). Other systems that use the data are called support systems (e.g. billing systems), Figure 6. To provide a comprehensive EHR, these systems must be linked, thereby allowing access to patient data regardless of their physical location. This introduces another level of complexity - system interoperability.

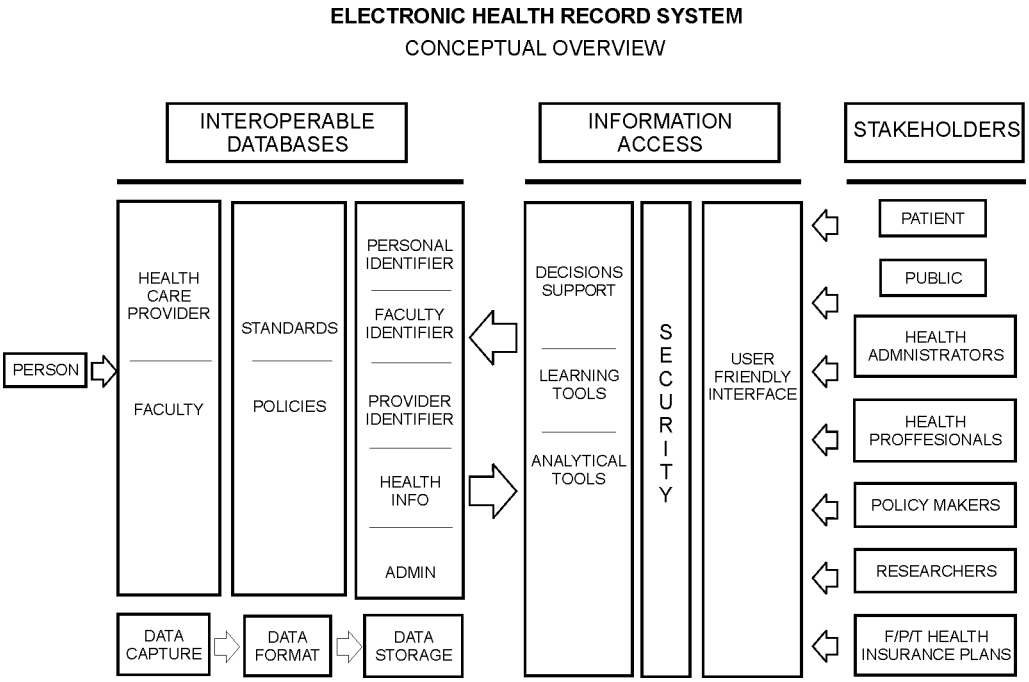
Figure 6. System network interoperability



Source: Toward Electronic Health Records. Office of Technology and Information Highway Canada, 2001 (13).

The Figure 7 presents the conceptual overview, divided into two major sections: the left side depicts the components involved in the creation of an EHR, and the right side identifies the users and tools required to access the Network. The creation of the Health Network (left side) involves the interaction of a person with a health care provider or health facility. The data are captured, subjected to standards and policies, and will then be stored with identifiers (person, facility and provider) as well as health and administrative data in interoperable databases. The right side of the Health Network illustrates how various stakeholders access the data stored in the databases by using user-friendly interfaces, security levels (to protect privacy and confidentiality) and various tools. In other words, once the requirements of an EHR are identified, an infostructure is required within which the EHR system will function. As previously stated, the EHR contains all health information generated by all the health care providers an individual interacts with over that person's lifetime. Each interaction will result in an Incident Record that will reside in a system. When these systems become interoperable, the building of the health infostructure begins.

Figure 7. Conceptual Overview of the EHR



Source: Toward Electronic Health Records. Office of Technology and Information Highway Canada, 2001 (13).

Necessary context blocks (identifiers and minimum data sets: health, administrative, medication and social data)

Electronic Health Record is the health record of an individual that is accessible online from many separate, interoperable automated systems within an electronic network. To facilitate this functionality, the proposed EHR would require next components (13):

Person Identifier: A universal code that uniquely identifies each individual (patient, person, citizen) within the health system.

Facility Identifier: A universal code that uniquely identifies each institution or centre that provides services within the health system.

Provider Identifier: A universal code that uniquely identifies each health care provider within the health system.

Health Information: Health data in a standardized format (e.g. diagnosis, x-rays, prescriptions) that are the result of interactions between individuals

and their health care providers. They are generated through health events in a form of event summaries.

Administrative Information: Standardized data that support administrative functions, such as billing.

As seen out of Australia and New Zaeland experience the core part of the EHR concept are *event summaries* - the underlying principle of electronic health records is that a useful picture of the health of an individual can be created from knowing key details of the *health events* that they have been involved in (14).

Event summaries provide an electronic overview of a health care event, such as a visit to a general practitioner or hospital. That is, they contain only the information that is relevant to the future health and care of health consumers, such as their condition, diagnosis and treatments, rather than every detail collected during a consultation. The collection of event summaries relating to an individual over time will constitute that person's electronic health record.

Given the large range in potential information processing that can, and often is undertaken by individual service providers, together with the almost infinite variability in the health status and requirements of individual patients at an encounter, it might appear counter-intuitive to prescribe or specify, *a priori*, what information should be captured under generic circumstances. However, just as the standardization of care processes through the use of evidence-based clinical guidelines has shown beneficial outcomes, so too, can the standardization of information recording potentially show benefits.

A key area of development work is the development of a framework that specifies what information should be included in event summaries and how this will be recorded. The framework should include the types of event summaries such as a health service discharge, prescription or diagnostic test result as well as defining what information is collected for such events. Event summaries would also need to accommodate the provision of care for groups as well as individuals, and would need to be appropriate to all care types and settings, for example: allied health, community nursing and rehabilitation, as well as hospital based inpatient and emergency.

EHR lists - Event summaries will provide information relevant to a specific consultation or event. It will contain details of a diagnosis or allergy identified as part of the consultation but will not include previous diagnoses or allergies. A view of the event summary will therefore not give a full picture of

the health status of the consumer. EHR lists are small collections of data describing key aspects of an individual's health for which there is a benefit in maintaining and viewing together. For example, it is important that allergies and alerts are viewed together rather than as part of numerous individual event summaries. EHR lists will enable data in event summaries to be stored in a fashion that allows rapid retrieval of the desired view through eliminating the need to hunt through all event summaries to find the information needed. EHR Lists will commonly form major components of EHR views. Populating EHR lists will also be the means by which a consumer's initial health profile would be created.

Examples of EHR lists include family history, risk factors, allergies and alerts, recent events, current medications list, current diagnoses and/or conditions, list of test results, and lists of care plans (14).

EHR views and reports - One of the major challenges of EHR model is to present the information collected in a useful and meaningful way to the specific requestor of the information. Core to the development would be the provision of a range of 'views'. Views would need to differ according to the provider type - specialists would be interested in different types of data to community health workers, and they will also need to differ depending on the issue being addressed. A chronological list of events would be of some, but limited, use. This simple approach would quickly overwhelm the viewer as he or she hunts through the event summaries to find the information needed. EHR model should be able to 'extract' relevant data from event summaries and present meaningful packages of information. The electronic health record lists will assist the development of key views (14).

An important division in the classification of these 'views' is the distinction between 'electronic health record views' and 'electronic health record reports'. Electronic health record views are designed primarily to serve the needs of the primary participants, that is, consumers and providers - and contain information about an identified individual. While 'reports', on the other hand, are designed to serve the needs of secondary participants, such as managers and researchers, and would usually take the form of aggregated data. Under controlled circumstances de-identified unit records could be provided for approved research. In some circumstances, an electronic health record view, that is, identified information, could be supplied to a secondary participant, for instance to a disease register where consent existed or reporting was required by legislation, or for research where a consumer has provided express consent for information to be provided.

Introduction of a *national health identifiers* to be used only in the health care sector under strict privacy protocols and which is to be implemented concurrently with EHR system should follow the basic principle - where the unified patient identification (UPI) is used for clinical or administrative purposes, as well as to link records for statistical purposes, the personnel who use the UPI for clinical or administrative purposes should not normally be able to access additional information on identified clients who have not consented to this access (14). Development of identification systems for providers, locations/facilities and possibly items of equipment (for example, MRI machines) is a part of a process which aims to identify the online security requirements for the electronic health records system such as access and usage controls.

Necessary building blocks (privacy, confidentiality and security; standards; telecommunication infrastructure; encouraging uptake and use of ICT)

(Note: The following text is taken from the National Electronic Health Records Taskforce Final report: „A Health Information Network for Australia". Commonwealth Department of Health and Aged Care, Australia, 2000 (14))

The best way to address objectives for electronic health records is to develop a general approach to health information exchange, rather than to build a structure designed just to support a system of electronic health records. This has to be achieved through putting in place the underlying 'building blocks', or infostructure components, that would be critical to underpin any national system of electronic health information interchange. Infostructure may be defined as: 'Information infrastructure for health that provides shared resources and standards for health care agents/parties that enable information to flow in appropriately structured, identifiable (unambiguous) and secure ways' (3).

The headings that define the building blocks are:

- privacy, confidentiality and security;
- standards (messaging and communications, data standards, coding and classifications);
- architecture; and
- encouraging uptake and use of information technology.

Privacy is a fundamental principle underpinning quality health care. With the uptake of new technologies, such as electronic health records, it will

be especially important that trust is maintained so that consumers can reap the benefits from improved information flow at the point of care, knowing that their privacy will be maintained.

The objective for privacy is the establishment of a uniform data protection regime across the country to apply to personal health information - a regime that enhances the privacy and respects the dignity of individuals. Health privacy is currently provided by a patchwork of legislation and administrative regimes. This means that there is no uniform health privacy protection for personal health information moving between the public and private sectors or across jurisdictional boundaries. This is an increasing problem, as the boundaries between the public and private sectors become less distinct in health care provision. Increasingly, single episodes of care involve multiple health care providers (such as general practitioners, diagnostic services and specialists) who may work in both the public and private sectors. It can then become unclear which privacy regime applies to any single practitioner, or any single episode of care.

Security and authentication - Specific standards and guidelines will need to be developed or modified to support the implementation of emerging policies and codes of practice for managing health information in an online environment. Appropriate security measures must be put in place wherever health information is collected and stored. With the increasing use of online information and communication technologies to facilitate the timely exchange of and access to health information, it is imperative that robust security measures support these processes to maintain and strengthen consumer and provider trust. Similarly, authentication measures must be in place when information is transferred or exchanged, to ensure that information is sent to the appropriate person at the correct destination.

The broad objective is to develop a sound security framework which mandates security standards for the health care sector to prevent unauthorised access to, and misuse of, online health information. It is expected that this will include security standards in the following areas:

- authentication of health care locations, individuals, health care workers and their roles;
- access;
- data management, transfer and use;
- data integrity; and
- system administration.

A further objective is to develop a comprehensive and coherent information security domain spanning the national health sector and incorporating the harmonisation of the security domains of major health agencies. These include Public Key Infrastructure (PKI) and Health eSignature Authority. PKI is the enabling technology that will allow for the provision of security for the online transmission of data including patient information. PKI provides a security mechanism that is used to facilitate online communication between the health sector and other health agencies such as the Health Insurance and the National Institute for Health. The Health eSignature Authority (HeSA) has to be established as an independent subsidiary of Health Insurance to facilitate the introduction of PKI in the national health sector. HeSA performs essential user identity checks before issuing digital certificates.

Standards activities - messaging and communications - Uniformity in messaging and communication standards and protocols, and consistent interpretation of these standards across the health sector is a crucial infostructure element. This is because information related to consumer health care is held in a variety of data formats and information structures using a range of health care computer applications as well as paper-based systems.

The development and adoption of common messaging standards will assist with the communication and sharing of consumer health information between disparate systems without customised interfaces. However, to achieve interoperability, agreed and implemented messaging standards will need to be supported by a number of other 'building blocks'. These include national data definitions and domains, terminology and coding, and identifiers. For example, interoperability will be considerably more difficult if two systems are exchanging messages using different coding schemes for medication types, or different means of patient identification. Achieving success with messaging interoperability nationally will thus depend on progress and outcomes of national strategies for other key standards and building blocks.

Standards activities - data standards, classification and coding systems - Explicit reference terminologies are necessary to allow health care providers to communicate, undertake business and share information electronically within and across sectors. National and international data standards are necessary to describe measure and communicate concepts about a person's health in ways which are uniformly understandable across the sector, and which will safely interface to decision support technology. Objectives of these activities are to:

- establish a sustainable process for the national maintenance of classifications and terminologies, and mechanisms to facilitate interoperability

through the use of an appropriate national reference terminology;

- agree upon national classification systems for all sectors identified within the framework (taking the WHO Family of Health Classifications work as a starting point); and
- establish a national mechanism for the assessment and accreditation of interface terminologies in use in all health care settings.

Standards requirements include at least:

- data definition (for example, expansion of the National Health Data Dictionary, National Minimum Data sets);
- health record architecture/structure (for example, Good Electronic Health Record, CEN 13606, HL7 Reference Information Model and Clinical Document Architecture, ISO/TS 18308);
- coding and classification, terminology (for example, ICD10, ICPC 2, LOINC, DRG, …);
- messaging and communication (for example, XML-Protocol, HL7, UN/EDIFACT, Corba);
- identification (for example, for client, health care provider, and location); and
- access control and security (encryption, public key infrastructure, security socket layer (SSL)).

Health information network architecture - A system of electronic health records will require appropriate infrastructure on which to run. Networks provide a physical channel for exchange of data between computers and have become commonplace in most settings heavily dependent on computer-aided assistance. Substantial groundwork is needed to ensure that it can deliver the potential benefits to all citizens in the most cost-effective and sustainable way. For each country, it will set the agenda for component development and the information and technology systems required to support these components that will work together to implement the overall system. The objectives for architecture are the establishment of a health information network architecture comprising source systems, event summaries, storage nodes/central services, applications and access points.

Electronic health record: architecture and information content - EHR model is conceived as an opportunity to develop and deploy basic health information infrastructure. Two closely related goals of health information exchange are important to this objective: (a) Interoperability - that is, the ability for records to pass between or be viewed by different systems (using diffe-

rent technologies, software, hardware and database platforms), and still be handled consistently, and, (b) Utility and Uniform understandability - that is, the appropriateness of and ability of the information content to be consistently interpreted across different settings, by different players, including by electronic decision-support tools without human intervention. To support these goals, and conscious of the need to maximise value adding of the information collected and stored, a crucial component is the use of standards to define the structure of the storage facilities wherever they are located. Unless a standard format is used for storage the value of the network will be seriously compromised - information will not be able to be shared, and the various network applications will not function.

The objective of standardisation of electronic health record architecture is to maximise the benefits of distributed information processing to be realised in an environment of heterogeneous information technology resources and systems, and multiple organisational domains. The International Standards Organisation (ISO)'s Reference Model for Open Distributed Processing states that: Building (distributed) systems is not easy. It requires an architecture and, because a single engineering solution will not meet all requirements, it must be a flexible architecture. Moreover, since a single vendor will not have all of the answers, it is essential that the architecture, and any functions necessary to implement the architecture, be defined in a set of standards, so that multiple vendors can collaborate in the provision of distributed systems. Such (architectural) standards will enable systems to be built that:

- are open - providing both portability and interworking;
- are integrated - incorporating various systems and resources into a whole without costly adhoc developments;
- are flexible - capable of both evolving and of accommodating the existence and continued operation of legacy systems;
- are modular - allowing parts of a system to be autonomous, but interrelated;
- can be federated - allowing a system to be combined with systems from different administrative or technical domains to achieve a single objective;
- are manageable;
- meet quality of service needs;
- are secure; and

- offer transparency - masking from applications the details and the differences in mechanisms used to overcome problems caused by distribution.

The advantages of a standardised EHR architecture include:

- maximising the ability of information to 'self-describe' to various systems, so that dependence on highly structured, 'static' interfaces is reduced;
- movement towards architectural convergence, as vendors increasingly comply with the standard, therefore increasing the ease of information interchange;
- establishing a common middleware specification for EHRs; that is, an EHR interoperability platform which takes care of difficult aspects of information processing and security, and allows application developers to concentrate on high quality applications; and
- the lifetime aspect of EHR will introduce the need for very long-term 'persistent' data. Information holdings that have been explicitly designed ('architected') to be self-describing or 'context conscious' but which are not explicitly linked to particular technologies, have a much greater chance of persisting - that is, moving into new technologies without unacceptable cost.

Encouraging uptake and use of information technology - Health care providers, who will bear the main responsibility for entering the information to form the basis of a national system of electronic health records, will need to be supported and encouraged in this vital work. This will mean assistance in acquiring the necessary hardware and software top connect to health information network, along with appropriate training and support.

Benefits of Electronic Health Records

Current paper-based record keeping means that valuable health information is not readily available where it is needed most - at the point of clinical care. Such 'information silos' inhibit major health care reforms aimed at achieving better integration and coordination of care. In this context, this concept aims to improve the flow of information across the health sector to ultimately improve the overall quality and safety of the health care system. Fully developed, EHR system would enable consumer health information to be collected electronically, safely stored and exchanged between authorised health care providers, within strict privacy safeguards.

Some of the anticipated, key benefits of EHR system include (13):

- empowerment of consumers through being able to access their own health information and therefore being able to make more informed decisions about their health care;
- reductions in adverse events through providers having rapid and improved access to critical patient information held elsewhere;
- improved provider access to evidence-based information at the point of care;
- efficiency gains through reduced time spent accessing information, together with reductions in unnecessary duplication of tests;
- better care coordination across the continuum through improved information flow between providers and services; and
- providing an invaluable evidence base for informing health care policy, planning and research activities, leading ultimately to more effective and efficient health care delivery nationally.

In addition to the obvious and vital benefits to individual consumers and their providers, better clinical information has an important role in securing long term benefits for all through improved policy, planning and management of the health system. Despite the myriad of different data collections that exist, there is still relatively little information readily available about how well any health care system actually delivers care, or the extent to which it actually improves health outcomes. The following table summarizes some of the potential benefits to different stakeholders (13).

Table 1. Stakeholder's benefits

STAKEHOLDERS	POTENTIAL BENEFITS
Public	Expanded reach of effective health care, More secure information, Improved sense of well-being, Access to information about how the health care system works
Patients or their representatives	Improved health care and decreased risks (e.g. adverse drug reactions), Integrated health services, Do not have to repeat basic information, such as name, address Increased confidence knowing that all health care professionals have access to all relevant parts of their medical history, Access to their own health records helps patients to make informed decisions about their health, Avoidance of duplicate, invasive and/or expensive tests, Reduced waiting lists
Health professionals	Integrated view of patient data, Increased access to other related and integrated patient information, Improved access through a portal to related health services, Improved decisions with up-to-date patient information on an as-needed basis, Improved seamless care through the coordination of multi-professional and multi-agency care, Improved development of decision support systems
Health administrators	Increased patient care time, Access to data to support clinical governance and local planning, Reduced health care costs, Improved health care quality
Policymakers (including governments)	Improves effective health maintenance and education, Supports medical and administrative decision-making processes, Provides for improved long-term planning
Researchers (including governments)	Access to timely high-quality data for research, Access to up-to-date research findings, treatment and medication options, Improved data quality, To aggregate data, Allows for improved trend analysis
Governments	Improved accountability, Improved health resource allocation

Source: Toward Electronic Health Records. Office of Technology and Information Highway Canada, 2001 (13).

Difficulties and risks associated with Electronic Health Records

However, while the benefits of EHR system are both readily accepted and understood by consumers, providers and policymakers, there are risks and barriers that would need to be addressed in implementing an initiative on the scale of EHR system. As evidenced by other's experiences, successful implementation of EHR system would require commitment at all levels of the health care system - from the end users right through to heads of government. Failure to obtain such commitment is likely to result in fragmentation and lack of connectivity across the health sector. In broad terms, issues to be overcome include (14):

- concerns about privacy, security and confidentiality of information in the system;
- gaining the acceptance of health professionals and other users;
- actual implementation;
- technical issues; and
- level of investment and political commitment required.

To address these issues (privacy, security and confidentiality of information in the system) would require a multi-layered approach to privacy and security, including both legislative and technical mechanisms for ensuring a robust privacy framework is in place for EHR system. Key to achieving acceptance of health professionals and other users includes: involving end users at all stages of development to ensure that EHR system meets user requirements providing education, training and support as part of an appropriately resourced, overarching change management strategy; and addressing identified medico-legal issues ahead of implementation.

When actual implementation is in question and having the rapidly changing health information environment, cooperation between the major parties, particularly state and district governments, is crucial to successful implementation of EHR system. Sustaining national cooperation requires adequate resorting in terms of both governance and project management. Other such risks to be addressed include: ensuring the EHR system design integrates with work practices; developing sustainable registration and identification processes; and ensuring standards development is given sufficient priority.

Technical issues include: lack of provider infrastructure, support and expertise; provider system changes too complex; internet reliability; insufficient or absent standards leading to greater maintenance effort once EHR system has been implemented; and poor management resulting in a flawed technical solution.

The level of funding made available for EHR system will determine the speed of implementation.

National approaches: examples

A number of countries and regions (in the case of Europe) have embarked on electronic health record initiatives. The European, as well as Australian and New Zealand experience, has been driven by the high percent of physicians who use computers in their practice - for example, over 90% of general practitioners in the Netherlands and the UK up to 58% in Portugal and 43% in Greece. The high use of computers by physicians in Europe and Australia has been supported by legislation and financial incentives. Only recently has the focus turned to hospital and regional EHR implementations.

The North American experience has had a different starting point from Europe - in hospitals rather than physician offices. This is in large part due to the large investment in commercial hospital-based information systems in North America and less focus on general practitioners.

In developing countries the key initiatives come from government and cover an introduction of health management information systems. But it is recognized that they should have a strong patient-centered orientation. For that reason they implicitly are looking for an electronic health record as a building block.

For countries in transition which generally are covered with amazing flow of health data, mostly in paper form, with well established health and social rights, but unfortunately with lack of money, informatization is seen as a one of the best infrastructure steps in overcoming the current situation.

The most notable electronic health record initiatives include (compiled mostly from: Health Connect Program Office. International Approaches to Electronic Health Record. Department of Health and Ageing. Commonwealth of Australia. 2003. www.healthconnect.gov.au and Canada Health Infoway. EHRS Blueprint – an interoperable EHR framework. Version 1.0. 2003. http://knowledge.infoway-inforoute.ca):

- **Europe** - Good European Health Record project, MEDIREC, PROREC initiative (for more information see: Electronic Health Records and Communication for Better Health Care. Proceedings of EuroRec 2001. Ed. Mennerat F. IOS Press 2002, and also www.chine.ucl.ac.uk/health/gehr and www.cenorm.be)
- **United Kingdom** - Information for Health, ERDIP (Electronic Record Development and Implementation Programme). See: www.nhsia.nhs.uk/erdip

- **The Netherlands** - See: Kieke, O 2002, 'Experience with Information Technology in Dutch health care: promises and pitfalls, global insights seminar', Healthlink, November 15-18, 2002, Monterrey, California.
- **Sweden** - See: Taylor, H and Leitman, R (eds) 2002, 'European Physicians Especially in Sweden, Netherlands and Denmark Lead US in Use of Electronic Medical Records', Harris Interactive Healthcare News, vol. 2, Issue 16.
- **Denmark** - See: Lippert S, Kverneland A. The Danish National Health Informatics Strategy. In: The New Navigators - from professionals to patients. R. Baud et al. (Eds). IOS Press 2003, and also at www.im.dk/Index/dokumentoversigt.asp
- **Ireland** - See: Information for Action. A National Health Information Strategy for 2002-2009. A consultation document. Draft 1. Department of health and children. 2001.
- **New Zealand** - See www.nzhis.govt.nz
- **Australia** - See www.health.gov.au/healthonline, www.gehr.org, www.healthconnect.gov.au, and next documents: Department of Health and Aged Care 2000, A Health Information Network for Australia, Report to Health Ministers by the National Electronic Health Records Taskforce, Department of Health and Ageing, Canberra, viewed at http: //www.healthconnect.gov.au/pdf_docs /ehr_rep.pdf; National Electronic Health Records Taskforce 2000, A Health Information Network for Australia: Report to Health Ministers, Department of Health and Aged Care, Canberra, viewed at http://www.healthconnect.gov.au/pdf_docs/ehr_rep.pdf
- **Hong Kong** - See: Yeoh, EK. Secretary for Health and Welfare, Hong Kong, Health services, policy objective and key result areas, at:www.policyaddress.gov.hk/pa01/pdf/healthe.pdf, www.hwfb.gov.hk/hw/english/archive/consult/HCS/HCS.HTM and www.info.gov.hk/hwb
- **United States** - See www.iom.edu
- **Canada** - See www.hc-sc.gc.ca/ohih-bsi and http://knowledge.infoway-inforoute.ca
- **South Africa** - See www.uneca.org/aisi/health1.htm and www.angelfire.com/ok3/peaceportal/telehealth.html

- **Brazil** - See: Lemos, M and de Faria Leao, B 2003, 'The Brazilian national health card project, NI2003: proceedings of the 8th international congress', Nursing Informatics 2003, June 20-25, 2003, Rio de Janeiro, Brazil.

EXERCISE: EHR Development - Data Storage, Data Privacy and Security

Task 1: Data Storage

Electronic Health Record (EHR) is representing personal health information in electronic form, which are following the patient from birth until death. In EHR information about health events - contacts of the patient/consumer with primary health care, are combined with health events - information about patient's contacts with all other health care levels. EHR is usually based on individual or family data, authorised health care professional is filling necessary information in EHR, and some of these information afterwards can be aggregated and distributed to other predefined EHR users, participants in the system. EHR is promoting data exchange about patient on higher level, so that health care professionals can communicate easily, everyday contacts between patient/consumer and doctor/provider are facilitated, accuracy of documents is upgraded, efficacy and quality of health care is also promoted, and, above all, infrastructure for decision making can be built, in the sence of evidence based decision making, based on information stored in electronic form.

Students should fill in the questionnaire and then discuss their attitudes in small groups, with presentation of summary in the plenary session.

In this questionnaire data are listed to be included in Electronic Health Record (EHR). Some data in EHR are permanent, long-life data, since others are changeble - they can be stored for one year period maximum. Please, mark with X which data can be permanent / changeble, according to your experience:

Information type	**Information storage period**		**Non-relevant information for EHR**
	Permanent	Up to 1 year	
Identification information (date, time, place, sex on birth, blood group)			
Administrative data: • Family name, middle name, name • Date and place of birth, sex • Address and phone number • ISO country code • Compulsory insurance • Name of employees establishment • Professional code No • Register No			

• Health insurance booklet No • Validity date • Insurance legal basis • Voluntary insurance • Type of insurance • Chosen doctor • Medical documentation No • Organ / body donor • EHR status • OTHER (please, specify):			
Social data: • Marriage status • Number of children, occupation • Education • Living conditions • Occupational status • Social support • Invalidement • Child - family social status • Life style (smoking, alcohol) • OTHER (please, specify):			
Medical data: • Drug allergies, vaccinations and serum if received • Congenital anomalies • Chronically diseases • Active form of TBC • Professional diseases • Surgeries performed • Current therapy (insulin, dialisys) • OTHER (please, specify):			
General Practitioner: • Electronic provider / consumer identification • Date, time and place Reason for event • Diagnosis: - Current - Principal • Intervention • Immunisation • Referrals • Prescription • Appointments • OTHER (please, specify):			

Ambulatory care: • Electronic provider / consumer identification • Date, time and place • Reason for event • Diagnosis: - Current - Principal • Pathology results • Intervention • Referrals • Appointments • OTHER (please, specify):			
Hospital: • Electronic provider / consumer identification • Date, time and place • Diagnosis: - Principal - Secondary, additional and complications • Injury (at work, place, cause of injury) • Pathology results • Therapy (drugs, surgery procedures, rehabilitation,recommendation) • Result of care - Healthy - Transfer in other hospital - Transfer on rehabilitation • Death - Time of death - Cause of death - Autopsy - result • OTHER (please, specify):			
Current medication list: • Date started to take drugs • Name of drug(s) • Dosage of drug(s) • OTHER (please, specify):			
List of recent pathology, radiology and laboratory test results: • Only the test results available in electronic form • OTHER (please, specify):			

Task 2: EHR Data Privacy and Security

Students will fill in the questionnaire and then discuss the possibilities in their own countries to implement EHR.

1. According to you, is it necessary to establish EHR under special legislative frame?

   yes no

2. According to recent legislative in health care system, it is very important to keep privacy and security of patient/health care consumer. Approach to data in EHR can be regulated on different levels. Some information can be available only to GP, some of them can be available to GP and to EHR owner - patient, and some of them are available to other EHR users (doctor - specialist, pharmacist, Health Insurance Fund, Social Insurance Fund, Ministry of Health, Institute for Public Health). Please, mark with X in the table / field below who can approach to data in EHR, according to you:

Information type	Ordinated GP	EHR owner (patient, consumer)	Doctor specialist in second health care level	Others (Pharmacist, Insurance, Ministry, Inst. for public health)
Identification data				
Administrative data				
Social data				
Medical data				
Current therapy				
Recent laboratory, radiology test results				

GLOSSARY OF KEY TERMS

Note: The following terms are defined according to the Canada Health Infoway Inc. (2003) (3). *EHRS Blueprint – an interoperable EHR framework*, Version 1.0. Available at: http://knowledge.infoway-inforoute.ca

Access Control - A security technology that selectively permits or prohibits certain types of data access based on the identity of the accessing entity and the data object being accessed. A process that determines who is given access to a local or remote computer system or network, as well as what and how much information someone can receive.

Architecture – 1. A software architecture is an abstraction of the run-time elements of a software system during some phase of its operation. A system may be composed of many levels of abstraction and many phases of operation, each with its own software architecture. 2. Architecture is a term applied to both the process and the outcome of specifying the overall structure, logical components, and the logical interrelationships of a computer, its operating system, a network, or other conception. 3. The software architecture of a program or computing system is the structure or structures of the system, which comprise software components, the externally visible properties of those components, and the relationships among them.

Authentication - In computer security, the act of identifying or verifying the eligibility of a station, originator or individual to access specific categories of information. In data security, a measure designed to provide protection against fraudulent transmissions by establishing the validity of a transmission, message, station or originator. In data security, processes that ensure everything about a teleprocessing transaction is genuine and that the message has not been altered or corrupted in transmission. In computer security, the process that verifies the identity of an individual as established by an identification process. In data security and data communications, both the prevention of undetected alteration to data and peer entity (mutual verification of each other's identities by communicating parties) authentication. A process verifying that users are who they say they are. An example of authentication is requiring users to identify themselves with a password.

Authorization – 1. Process of determining what activities are permitted, usually in the context of authentication. 2. The permission to perform certain operations or use certain methods or services. 3. The process that grants access to a local or remote computer system, network or to online information.

Business Architecture - Defines the organization and functions of the business and the business processes that support those functions.

Business Process - A set of interacting activities that produce one or more products or services for customers of the business enterprise.

Clinical Data - Any information element obtained during an encounter relating to the assessment of a client's health state, diagnostic of diseases and/or treatments.

Clinical Data Repository - An operational data store that holds and manages clinical data collected from service encounters at the point of service locations (e.g. hospitals, clinics, etc.). Data from a CDR can be fed to the EHR for that client, in that sense the CDR is recognized as a source system for the EHR.

Clinical Information System - A clinical information system is a system dedicated to collecting, storing, manipulating and making available clinical information important to the delivery of healthcare. Clinical information systems may be limited in scope to a single area (e.g. lab system, ECG management system) or they may be comprehensive and cover virtually all facets of clinical information (e.g. electronic patient/person the original discharge summary residing in the chart, with a copy of the report sent to the admitting physician, another copy existing on the transcriptionist's machine, etc.)

Clinically Relevant Data - Any clinical data about a client that is deemed necessary or desirable to have available during an encounter. Relevance is expressed in relation to different perspectives set by factors such as disciplines in healthcare practice or context around an episode of care or elapsed time. Therefore relevance of data varies greatly and is hard to assess firmly.

Coding - The process of assigning an alphanumeric code to a concept in accordance with an agreed classification system e.g. ICD10 (International Classification of Disease version 10).

Conceptual Architecture – 1. A general design that indicates the overall intent and outline of the target architecture, architecture lays the foundation and defines the process that will be used to develop the target architecture. 2. A Conceptual Architecture describes or defines a technology solution at the functional level, without regard to a particular physical implementation. The Conceptual Architecture is used to create a comprehensive view of the system components, relationships, and interfaces needed to meet a technology requirement.

Confidentiality – 1. A security technique that permits read access and retrieval by authorized entities only. 2. Confidentiality protects the privacy of information being exchanged between communicating parties. In computer security, a concept that applies to data that must be held in confidence and that describes the status and degree of protection that must be provided for such data about individuals as well as organisations.

Consent - Explicit granting of access to specified information.

Continuum of Care - A holistic approach to healthcare delivery across multiple providers, aiming to improve the quality of care and promote wellness.

Data Model - Describes the organization of data in an automated system. The data model includes the subjects of interest in the system (or entities) and the attributes (data elements) of those entities. It defines how the entities are related to each other (cardinality) and establishes the identifiers needed to relate entities to each other (primary and foreign keys). A Data Model can be expressed as a Conceptual, Logical, or Physical model.

Data Warehouse - A database of information intended for use as part of a decision support system. The data is typically extracted from an organization's operational databases.

Database Management System - Systems that manage large structured sets of persistent data, offering ad hoc query facilities to many users. They are widely used in business applications: commercial examples include DB2, Oracle, SQL-Server, Sybase etc.

Decision Support System - Software that taps into database resources and massages and presents data to assist users in making business decisions. A clinical decision support system gives physicians structured (rules-based) information to help make decisions on diagnoses, treatment plans, orders and results.

De-identified data - Data are termed 'de-identified' when an individual's identity is not apparent, and cannot reasonably be ascertained by the user, from the record elements. Guidelines for de-identification and the use of de-identified information will be required.

Digital Certificate - A digital document issued by a certification authority that contains the holder's name, serial number, public key and the document's expiration date. Digital certificates are used in public key infrastructure to send and receive secure, encrypted messages.

Digital Signature - An electronic equivalent of a signature used to verify authorship or information source.

Domain Data - Clinical data that is specific to a particular domain. (e.g. drug, lab, diagnostic imaging, etc.)

Domain Repository - A Domain Repository is a component of an EHRi that stores, maintains and provides access to specific clinical subset of data at a jurisdictional level. The key data domains recognized as part of an EHR are drugs, laboratory and diagnostic imaging. In Canada today, some of these data domains may be already deployed as jurisdictional level systems in given jurisdictions. An EHR Infostructure must be able to assemble information transparently from these domains in order to provide the complete clinical picture of a patient/person.

EHR – Data. The collection of all important clinical data related to a particular patient/person.

EHR Infostructure - Collection of common and reusable components in the support of a diverse set of health information management applications. It consists of software solutions for the EHR, data definitions for the EHR and messaging standards for the EHR.

Electronic Health Record - 1. An Electronic Health Record (EHR) provides each individual in country with a secure and private lifetime record of their key health history and care within the health system. The record is available electronically to authorized health care providers and the individual anywhere, anytime in support of high quality care. 2. In an EHRi, the EHR is the central component that stores, maintains and manages clinical information about patients/persons. The extent of the clinical information sustained by the EHR component may vary based namely on the presence or absence of Domain Repositories in any given jurisdiction.

Electronic Health Record System - Combination of people, organizational entities, business processes, systems, technology and standards that interact and exchange clinical data to provide high quality and effective healthcare.

Electronic Patient Record - Electronic set of information about a single patient/person. An Electronic patient record system is a system specifically designed to provide patient/person records electronically. This is not necessarily restricted to a single clinical information system.

Encounter - An Encounter is a service event that occurs within an Episode of Care.

Enterprise Architecture - A framework that defines the overall structure of a business. It uses different perspectives or views such as business processes, information, systems and technology required to operate a business.

Enterprise Master Patient Index / Enterprise Master Person Index - An EMPI (Enterprise Master Person Index) is a system which coordinates client identification across multiple systems namely by collecting and storing IDs and person-identifying demographic information from source system (track new persons, track changes to existing persons). These systems also take on several other tasks and responsibilities associated with client ID management.

Episode of Care - An Encounter or series of Encounters related to the detection and subsequent care for a particular healthcare requirement.

Extensible Mark-up Language - XML is a mark-up language for structuring arbitrary data based on element tags and attributes. Describes a class of data objects called XML documents and partially describes the behavior of computer programs which process them. XML is an application profile or restricted form of SGML, the Standard Generalized Mark-up Language [ISO 8879]. By construction, XML documents are conforming SGML documents.

Facility - A type of Delivery Site that has constant capability and capacity to provide health services, and is administered by a health service organization.

Feeder Systems - Operational systems that will feed patient/person data to the EHR in the form of real-time single, multiple messages or batch file uploads.

File Transfer Protocol – 1. A standard high-level protocol for transferring files of different types between computers over a TCP/IP network. FTP can be used with a command line interface or graphical user interface. 2. The name of a utility program available on several operating systems which makes use of this protocol to access and transfer files on remote computers.

Framework - In object-oriented systems, a set of classes that embodies an abstract design for solutions to a number of related problems. Frameworks can be horizontal or vertical. An example of a horizontal framework is the Presentation framework (GUI); and example of a vertical framework is a business accounting framework.

Health Information Access Layer - The Health Information Access Layer is an interface specification for the EHR Infostructure (OSI Layer 7) that defines service components, service roles, information model

and messaging standards required for the exchange of EHR Data and execution of interoperability profiles between EHR Services.

Identifiable data - Data are termed 'identifiable' when an individual's identity is readily apparent, or can reasonably be ascertained by the user, from the record elements.

Identification - A person identifier is a universal code that uniquely identifies each individual of consumers, within the health system. Such an identifier can be simply assigned or based providers, locations/ on some unique characteristic of the individual (called biometric identification) facilities and devices. Similarly providers, facilities, individual devices and the location of the point of care may all have to be capable of unequivocal identification to guarantee the integrity of a system of electronic health records.

Implementation - Implementation is the carrying out, execution, or practice of a plan, a method, or any design for doing something. Implementation is the action that must follow any preliminary thinking in order for something to actually happen.

Information Model - A structured specification of the information requirements of a project. An information model expresses the classes of information required and the properties of those classes, including attributes, relationships, and states. Examples are the Domain Reference Information Model, Reference Information Model, and Refined Message Information Model.

Infostructure - This is a concatenation of the phase INFOrmation infraSTRUCTURE. It covers both physical (e.g. computers and cables) and abstract (e.g. standards, data sets, terminologies, workforce capacity) infrastructure elements.

Internet - The internet is behind much of the explosive growth in data communications. Often characterised as a network of networks, the internet is a set of protocols for enabling computers to connect and communicate with each other. Viewed in another way, it is like a communications platform that enables a range of other, internet-specific programs to run. A major stimulus to growth in recent years has been the universal adoption of the hypertext transport protocol (HTTP) and the easy-to-use web browsers that emerged to exploit it. Indeed, so ubiquitous is web-browsing-based internet usage that for many people the internet and the World Wide Web are synonymous. Indeed, given the ability of web-browsers to emulate a wide range of more function-specific client programs (e.g. email), many other internet programs have, fact, been absorbed into browser-based functions. The internet was not originally designed with businesses in mind. It lacks the technology required for secure business communications and transactions. A worldwide system of computer networks. Networks connected through the internet use a particular set of communication standards, known as TCP/IP, to communicate.

Interoperability – 1. The ability of hardware and software from different vendors to understand each other and exchange data, either within the same network or across dissimilar networks. 2. The ability of autonomous systems to work with other dissimilar systems. Interoperable systems interact through standardized interfaces. They are often loosely coupled and exchange information in an asynchronous manner. Interoperable systems can function without knowing the internal processes, functions, and data representations of other systems. The ability of two or more systems to exchange information or function together.

ISO - International Organization for Standardization. Note that ISO is not an acronym; instead, the name derives from the Greek word „isos" which means equal. Founded in 1946, ISO is an international organization composed of national standards bodies from over 75 countries. For example, ANSI (American National Standards Institute) is a member of ISO. ISO has defined a number of important computer standards, the most significant of which is perhaps OSI (Open Systems Interconnection), a standardized architecture for designing networks.

Logical Observation Identifiers, Names and Codes - A database protocol aimed at standardizing laboratory and clinical codes for use in clinical care, outcomes management and research. Developed by the Regenstrief Institute for Health Care, LOINC is touted as a middleman solution to potential translation problems between labs that use HL7 reporting and recipient systems that may not be able to translate such data.

Longitudinal - Involving the repeated observation or examination of a set of subjects over time with respect to one or more study variables (as general health, the state of a disease, or mortality).

Longitudinal Record - Patient/person centric electronic health information spanning from the earliest event to the most recent encounter.

Message - A package of information communicated from one application to another.

Messaging - The activity and associated processes of sending or receiving a message.

Metadata - Data about data. Metadata describes how and when and by whom a particular set of data was collected, and how the data is formatted. Metadata is essential for understanding information stored in data warehouses. Data definitions describing aspects of the actual data items, such as name, format etc.

Middleware - Software systems that facilitate the interaction of disparate components through a set of commonly defined protocols. The purpose is to limit the number of interfaces required for interoperability by allowing all components to interact with the Middleware using a common interface.

Model - A representation of a problem or subject area that uses abstraction to express the relevant concepts. A model is often a collection of schema and other documentation.

Modularity - The design goal of separating code into self sufficient, highly cohesive low coupling pieces.

Network - In information technology, a network is a series of points or nodes interconnected by communication paths. Networks can interconnect with other networks and contain sub-networks.

Nodes - In a network, a node is a connection point, either a redistribution point or an end point for data transmissions. In general, a node has programmed or engineered capability to recognise and process or forward transmissions to other nodes.

openEHR - *Open*EHR, formerly known as the Good Electronic Health Record, provides an open architecture and a standard format for electronic health records.

Open Source Software - Open source refers to any program whose source code is made available for use or modification as users or other developers see fit. OSS is developed as a public collaboration and made freely available. Definition model of distribution terms require that: (1) The software must be redistributed without any restriction, (2) The source code must be made available (3) The license can require improved versions of the software to carry a different name or version from the original software. Linux is the most common form of OSS.

Open Systems Interconnection - A seven-layer reference model developed by ISO as a framework for the development of standards for interconnecting heterogeneous computers. The layers from the top are Application, Presentation, Session, Transport, Network, Data Link and Physical.

Person Centric/Patient Centric - A design goal or characteristic that establishes that all information in an application system shall be grouped and/or indexed according to the patient/person. Person Centric Patient Centric.

Privacy - Freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of about that individual.The right of an individual to live free of intrusive monitoring of their personal affairs by third parties not of their choosing.

Privacy Enhancing Technologies - Technologies used to protect privacy rights and secure transactions on the Internet or other networks. It includes methods such as encryption, digital signatures and digital certificates as well as both private and public key methods encryption environments.

Provider - Any supplier of a healthcare service.

Provider Registry - A Provider Registry is a system or a combination of systems where a health care

provider's information (i.e. name, address, practice licences, etc…) is securely stored, maintained and made available to other systems and users.

Public Key Infrastructure - The architecture, organization, techniques, practices and procedures that collectively support the implementation and operation of a certificate based public key cryptographic system. Public Key Public Key Infrastructure (PKI) is a set of procedures and technology that Infrastructure (PKI) enables users of a network such as the internet to authenticate identity, and to securely and privately exchange information through the use of public key cryptography. To achieve this, public and private keys and a digital certificate can be obtained through a trusted third party authority, known as a certification authority (CA). The CA links the public key to the digital certificate and vouches for the identity of the key holder. In order for the system to operate, a process must be established to accurately identify a person via something like a 100 point test. Registration authorities (RAs) undertake this role by collecting and managing the appropriate levels of Evidence of Identity (EOI) from applicants for digital certificates. Dependent upon the PKI business model employed, appropriately accredited RAs may also create keys and certificates. The use of PKI ensures authentication, integrity, non-redudiation and confidentiality for e-commerce applications.

Reference architecture - Generalized architecture of several end systems that share one or more common domains. The reference architecture defines the infrastructure common to the end systems and the interfaces of components that will be included in the end systems. The reference architecture is then instantiated to create a software architecture of a specific system. The definition of the reference architecture facilitates deriving and extending new software architectures for classes of systems. A reference architecture, therefore, plays a dual role with regard to specific target software architectures. First, it generalizes and extracts common functions and configurations. Second, it provides a base for instantiating target systems that use that common base more reliably and cost effectively.

Registration Authority - A registration authority is an authority in a network that verifies user requests for a digital certificate and tells the certificate authority (CA) to issue it. RAs are part of a public key infrastructure (PKI), a networked system that enables companies and users to exchange information and money safely and securely.

Registry - Directory like system that focuses solely on managing data pertaining to one conceptual entity. In an EHRi, registries store, maintain and provide access to peripheral information not categorized as clinical in nature but required to operationalize an EHR. The primary purpose of a Registry is to respond to searches using one or more pre-defined parameters in order to find and retrieve a unique occurrence of an entity. Examples of registries include: Client Registry, Provider Registry, Location Registry, and Consent Registry.

Scalability - The ability to support the required quality of service as load increases.

Security - The ability to ensure that information is neither modified nor disclosed except in accordance to the security policy.

Security Architecture - A plan and set of principles for an administrative domain and its that describe the that a system is required to provide to meet the needs of its users, the system elements required to implement the services, and the performance levels required in the elements to deal with the threat environment. A complete security architecture for a system addresses administrative security, communication security, computer security, *emanations security*, personnel security, and physical security, and prescribes security policies for each. Complete security architecture needs to deal with both intentional, intelligent threats and accidental threats. Security architecture should explicitly evolve over time as an integral part of its administrative domain's evolution.

Systems Architecture - Describes how the business process models defined in the Business Architecture can be implemented from a systems (data, applications and technology) perspective.

Technical architecture – 1. A technical architecture identifies and describes the types of applications, platforms, and external entities; their interfaces; and their services, as well as the context within which the entities interoperate. The technical architecture is the basis for selecting and implementing the infrastructure to establish the target architecture. 2. The specific code plans to build an IT solution is called the Technical Architecture. It is the IT „blue print" of the planned technical roll out.

Virtual Private Network - Refers to a network in which some of the parts are connected using the public Internet, but the data sent across the Internet is encrypted, so the entire network is „virtually" private. A VPN is a data network that adds certain quality-of-service features, at least network (VPN) privacy and security, to the internet. An internet-based system for information communication and enterprise interaction. A VPN uses the internet for network connections between people and information sites. However, it includes stringent security mechanisms so that sending private and confidential information is as secure as in a traditional closed system.

Web Services - An application capable of being defined, located via the Internet protocol, and interacting with other software applications, identified by a Uniform Resource identifier.

Web Services Description Language - Provides a model and an XML format for describing Web services. WSDL enables one to separate the description of the abstract functionality offered by a service from concrete details of a service description such as „how" and „where" that functionality is offered.

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Recommended Readings

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Health Indicators and Health Reporting**
Module: 1.4	**ECTS (suggested): 0.50**
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Keywords	Health Indicators, Health Indicator Sets, Health Reporting, HFA 21, New Public Health Programme of the European Union
Learning objectives	At the end of the module, the students should be familiar with: • public health-oriented health data and their interpretation; • different kinds of indicator sets; • definition/Characteristics of basic indicators; • use of indicators for health reporting; • use of indicator sets for policy-making.
Abstract	This topic covers: Different indicator sets; Classification and evaluation methods of indicators; Comparison methods and benchmarking; The use of health indicators for health reporting and health policy.
Teaching methods	The recommended teaching method is: • Study of literature and available health indicator databases in small groups (3-4 students) • Guided discussion of a health indicator set for a certain region (examples) • Use and presentation of health indicators in a health report • Exercise: to collect data from public health databases, to prepare a health report on one topic for a certain region (e.g SEE or CEE countries)
Specific recommendations for teachers	It is recommended that this module be organized within 0.50 ECTS credit. The work under supervision consists of lecturing and use of the HFA database, while individual work will comprise the selection of a set of indicators from the HFA database and use of the data for health reporting and health policy. Each of the students or at least two students need a PC with Internet-connection. Data on health statistics and software must be available.
Assessment of students	Essay on priority setting based on indicator analysis for a certain country/region.

HEALTH INDICATORS AND HEALTH REPORTING

Doris Bardehle

Classification and evaluation method of indicators

This lecture follows the lines of the documents of WHO, Regional Office for Europe, and of the European Union, based on the New Public Health Programme (2003-2008) and the former Health Monitoring Programme (HMP):

- New Public Health Programme 2003-2008: Action Programme of the European Union in the field of Public Health for the year 2003 (1).
- „Set of Community Health Indicators (ECHI I)" of the European Commission (2).
- „Catalogue of Health Indicators" of the HFA 21 - Health for All Strategy (3).
- „Health Interview Survey" of WHO, Regional Office for Europe (4).
- „Common Minimum Indicator Set". WHO Europe. Regions for Health Network (5).
- „Establishment of a set of mental health indicators for the European Union" (6).
- „Reproductive Health Indicators for Global Monitoring". WHO Geneva (7).
- „Minimum Health Indicator Set for PH-SEE Countries". Final Report (8).

The types of different indicator sets

A design for a „Set of Community Health Indicators (ECHI I)" was developed by the European Commission under the Health Monitoring Programme (HMP) which contributes to the establishment of a Community health monitoring system in order to:

1. Measure the health status, its determinants and trends throughout the Community;
2. Facilitate the planning, monitoring and evaluation of Community programmes and actions;
3. Provide Member States with appropriate health information to make comparisons and support their national health policies (2, p.5).

The New Public Health Programme of the EU replaces all former public health programmes. It will focus on three types of activity:

1. To improve the quality and transparency of health information;
2. To improve current abilities to respond rapidly to health threats; and
3. To find effective ways to tackle health determinants – the underlying causes of disease (9, p.1-3).

The New Public Health Programme will provide policy makers, health professionals and the general public with the key health data and information that they need. The programme will primarily transmit and act on new information about health threats that require immediate action to prevent further harm. Instead of concentrating on specific diseases, actions addressing health determinants will tackle the root causes of diseases or „health determinants" through effective health promotion and disease prevention measures. Under the Health Monitoring Programme, the European Community Health Indicators (ECHI I) Project was developed. Under the New Public Health Programme, the ECHI project will be continued and a final version be expected (ECHI II).

With regard to the preparation of the „Health 21 – Health for All Strategy for the 21st Century", the development of a new „Catalogue of Health Indicators" was started by WHO. Meanwhile this catalogue has been published and contains around 200 indicators (3).

Indicators on reproductive health developed by WHO Geneva relate to the health indicators' methodological concept of WHO, too (7).

Eurostat, the Statistical Office of the EU is responsible for coordinating health statistics as causes of death statistics, health interviews and health examination surveys and health care data groups. Population data are included in the new Cronos database. Via a public health portal (controlled by the Commission services), health data will be presented within the EU Public Health Information Network and include databases such as EUPHIN HIEMS which was established under the HMP Programme and continued under the New Public Health Programme (1).

One of the sources of health indicators is the Health Interview Survey (WHO Europe, 1996) and the Health Examination Survey, which have meanwhile been internationally harmonized in terms of methods and instruments used (4). Meanwhile the database of health surveys conducted in the EU Member States is available on the Internet at URL: http://www.iph.fgov.be/hishes.

The survey methods, the content of the questionnaire and the examination protocol are available through the database and can be compared from one country to another. With the support of Eurostat the inventory will now be extended to include the candidate countries.

Measurement and reporting of health conditions and actions for health improvement through „internationally agreed" indicators have been a favorite strategy of international organizations. WHO used this concept for promoting the Health For All concept strategy (see health indicators for HFA 2000 and HFA21 (R1 and R2)). The result has been a long list of indicators to be collected by the countries and to be delivered to international organizations.

The development of a Minimum Data Set of European Mental Health Indicators was the result of a two-year action project, aimed at establishing mental health indicators in Europe, coordinated by Stakes (Finland) (1999-2000). Under the Health Monitoring Programme, a subset of health indicators was developed in the field of mental health indicators, published in 2002 and based on the same rules as the ECHI I indicator set (6).

A list of 36 indicators was developed and proposed for usage in Europe. The 36 indicators are divided into the following main domains:

1. Demographic and socio-economic factors
2. Health status
3. Determinants of health
4. Health systems

To determine the volume of essential health indicators for monitoring the health status and health system performance lies within the responsibility of each country and has to be done in accordance with specific health policies. Now new proposals have been made for health indicator sets issued by WHO, the EU countries and organizations which make it difficult to select a defined indicator set to be used (7,8,10,11,12). It is not proven which indicators are useful and feasible for the national health programmes' management process.

Within the framework of the Stability Pact, a Minimum Indicator Set was developed for the South Eastern European countries which started in 2001 (8). The draft of the Minimum Indicator Set was based on the experience made collected with the Common Minimum Indicator Set (CMIS) of the Regions for Health Network, WHO-EURO, agreed with 8 European regions in 1999 and selected from a list of 224 indicators for the WHO HFA 21 strategy (5).

The indicators for the pilot testing carried out in 2002 covered:

- *the socio-demographic profile* (percent of population aged 65+ years),
- *mortality* (life expectancy at birth, in years, males/females; infant mortality rate; maternal deaths, all causes; standardised death rate-SDR, circulatory system diseases, all ages, males/females; SDR malignant neoplasms, all ages, males/females; SDR external causes injury and poison, all ages, males/females; SDR infectious and parasitic diseases, all ages, males/females)
- *morbidity* (number of newly diagnosed tuberculosis cases, all forms; number of decayed, missing or filled teeth at age 12)
- *environment* (percent of population whose homes are connected to water supply system, total; percent of population with access to hygienic on sewage disposal, total)
- *health care resources* indicators,(number of primary health care units per 100,000 population; number of hospital beds per 100,000 population; number of physicians per 100,000 population; number of general practitioners in PHC per 100,000 population; number of dentists per 100,000 population; number of nurses graduated per 100,000 population)
- *health care utilisation and costs* (average length of stay, all hospitals; total health expenditures as percent of gross domestic product)
- *maternal and child health* (percent of infants vaccinated against diphthe-

ria; percent of infants vaccinated against tetanus; percent of infants vaccinated against pertussis; percent of infants vaccinated against measles; percent of infants vaccinated against poliomyelitis)

This indicator set contains 30 indicators. All indicators which were included in the list, had to reflect the special situation of the South Eastern European region (SEE).

After the pilot phase, 22 of the selected indicators proved to be qualified enough to reflect the health and social as well as health care situation in the PH-SEE countries. 8 indicators did not meet the quality criteria for an indicator or had to be replaced because of the poor data situation. Other indicators had to be added after analysing the health situation within the PH-SEE countries and in consideration of the main topics of health policy (8).

The indicators have to meet specific criteria such as:

- relevant (regarding priorities)
- valid (regarding determinants of health)
- measurable (in quantitative and qualitative terms)
- sensitive (to changes and differences)
- comparable (inter-territorial)
- repeatable (for time series)
- affordable (in terms of relative costs)
- useful (for intervention)
- ethical (e.g. respect personal autonomy)

Definitions for all above-mentioned indicators are available at http://www.who.dk/country/HFAdbbook.pdf (R3)

The following chapters will help to explain the meaning and composition of an indicator set.

Indicator classification and evaluation methods

Definitions of „Health Indicators" (www.who.deficrit.htm*)*

Indicators are markers of the health status, healthcare system performance or availability of resources, defined in a way to allow the monitoring of objectives, targets and performance. Thus they cannot be confused with *objectives and targets.* Objectives are statements aiming to improve health or to reduce the frequency of certain diseases, expressed in a quantitative manner, within a given time frame. Targets are usually expressions of the desired service performance, for example, output or coverage, desired to be achieved at some time point in the future.

Indicators are defined as variables able to measure the changes in the level of health target achievement i.e. Health for All (HFA) targets.

Indicators are used for health monitoring and health surveillance.

Health monitoring is defined as the maintenance or regular checking of ongoing activities or programmes with respect to predefined objectives. The purpose is to record what the system is actually achieving at present and to detect possible deviations from the decided course of action.

Surveillance refers to the ongoing observation of the health status of a population and the factors that may affect it, and its purpose consists in detecting possible changes at an early stage and initiating appropriate action (4, p.4).

Types of indicators

There are three types of HFA indicators which are defined in the HFA 21 catalogue of health indicators (3). Definitions and criteria are:

1. outcome (health status or death)
2. process (health care delivery and management, including resources)
3. determinant (e.g. behavioural factors and public knowledge)

All HFA 21 indicators (3) can be used to measure progress towards established targets and goals, including the monitoring of changes in the health status of the population. Most of them can be used to monitor service performance at the facility, district and national levels.

Generic indicators are broadly defined areas of measurements linked to specific parts of the HFA policy framework (HFA targets) and traditionally constitute an integral part of the HFA policy document.

Operational indicators are precisely defined numerical data items as recorded in the HFA statistical database (3).

An indicator can be defined at the generic level, e.g. „smoking behavior", or in an operational manner, e.g. „% of women in x age group, x smoking between y and z cigarettes per day". Operational indicators are always expressed in a numerical way, calculated from primary data in a more or less complex manner. An example of a complex calculation is „life expectancy at birth", which is calculated from a large set of age-specific mortality data.

Indicators are usually numerical (rations, proportions, rates), although they can also be qualitative (e.g. existence or absence of a sign, event, etc. that has been shown to be important).

Quality criteria for health indicators

With regard to the selection of indicators, the following prerequisites are necessary:

- The actual selection and definition of indicators within a specific public health area should be based on *scientific principles.*
- Indicators (and underlying data) should meet a number of methodological and quality criteria concerning e.g. *quality, validity, sensitivity and comparability.*

- The probability of changing policy priorities/interests calls for a *high degree of flexibility,* made possible through current electronic database systems.
- The selection of indicators should be based on existing and comparable data sets for which regular monitoring is feasible, but should also indicate *data needs* and *development areas* (2).

The quality of indicators will be measured according to the following four criteria:

1. *Validity:* i.e. it is a true expression of the phenomena it is measuring;
2. *Objectivity:* i.e. it is able to provide the same result if measured by different people under similar circumstances;
3. *Sensitivity:* i.e. it is capable of reflecting changes in the phenomena of interest;
4. *Specificity:* i.e. it reflects changes in the specific phenomena of interest only.

Additionally, the following criteria are relevant for the use of an indicator and the methodology employed to collect the data:

- The data required for the indicator are useful for case management or taking action in the community for the staff who originally recorded the data, or the service unit from which the data originated.
- It should be feasible to obtain the data needed for each indicator and that these data should be generated, as far as possible, through routine service processes or through easily and rapidly executable surveys.
- The indicators should be simple and understandable, measuring a health condition or aspect of service. Composite indicators should be avoided.
- The indicator and the process of collecting and processing the relevant data are ethical (3).

Health indicators serve several purposes:

1. They are an important tool of for health policy formulation and implementation.
2. They are used to track progress, i.e. they are used for monitoring and evaluating the health situation with respect to specified objectives.
3. They can provide yardsticksbenchmarks whereby countries can compare their own progress with that of other countries, especially those at similar levels of socio-economic development.
4. They cannot be measured at present because no adequate information is in place; they are nevertheless adopted for use because they point to what needs to be done (guidance for action, including information systems' development).

5. Indicators have a communication and coordination function: for example, when decided in a proper consultation process they constitute an important message to the community about agreed priorities (4, p.7).

Main categories of an indicator set

The following main categories of a set of Community Health Indicators (ECHI Indicator set) were proposed:

1. Demographic and socio-economic factors

1.1. Population
1.2. Socio-economic factors

2. Health status

2.1. Mortality
2.2. Morbidity, disease-specific
2.3. Generic health status
2.4. Composite health status measures

3. Determinants of health

3.1. Personal and biological factors
3.2. Health behaviors
3.3. Living and working conditions

4. Health systems

4.1. Prevention, health protection and health promotion
4.2. Health care resources
4.3. Health care utilization
4.4. Health expenditures and financing
4.5. Health care quality / Performance

The European Commission (2, p.12) developed a concept according to which indicators can be divided into the following categories:

1. *Cockpit information:* to have a quick view on the major trends in public health, including recent relevant signals, for medium or long-term policy strategies;
2. *EU priority list*: to follow developments for specific EU policy areas or targets, programmes or projects;
3. *The WHO / HFA 21 indicator set:* to follow this list of indicators for the EU countries;
4. *Health and services for mother and child:* to focus on reproductive health, health of children and family structure.

WHO Regional Office for Europe revised the indicator list during the transition period from HFA 2000 to Health 21 (3). The main change was a reduction in the total number of generic indicators from 112 to 59. About 50 indicators from HFA 2000 have been maintained and 9 new indicators have been adopted. The current indicators will cover such fields as:

- health status,
- health determinants, and
- socio-economic background.

The operational indicators of the Health 21 strategy are divided into the following groups (3, p.5)**:**

mortality,
morbidity,
disability,
maternal / child health,
other health status indicators,
lifestyle,
environment,
health care resources,
health care utilization,
quality of care,
health expenditure, and
demographic and socio-economic indicators.

Data for indicators are being collected from various sources (HFA 21). The main information sources are:

- Comprehensive statistical records already established for health or other purposes
- Ad hoc investigation or surveillance systems within the health services and
- Population surveys

All efforts are made to use information from available sources to avoid duplicating requests to countries.

In 1988, 1990 and 1992 the WHO Regional Office for Europe and Statistics Netherlands organized consultations to develop common methods and instruments for a health interview survey at the European level (4). The objective was that this health interview survey should be used countries in order to achieve better international comparability and enhance the value and use of survey results.

Recommended instruments for health interview surveys are:

01. Perceived health
02. Temporary disability
03. Long-term disability
04. Disability-free life expectancy
05. Chronic conditions (mental)
06. Smoking
07. Physical activity
08. Birth weight
09. Breast-feeding
10. Body-Mass-Index
11. Socio-economic classification (education, wealth, income, occupation, economic position).

Methods of comparison and benchmarking

The application of statistical methods will be the subject of other parts of the curriculum. To complete the establishment of indicator sets and use of health indicators, it has to be mentioned that comparability must be guaranteed with the help of the following methods. The use of statistical methods for comparing data of different regions includes:

- age standardisation incl. calculation of confidence intervals,
- significance check-ups,
- definitions of the included regions concerning the application of further statistical methods,
- calculations such as „PYLL: Person years life lost“,
- calculations for time trends, and
- meta-database description of the data used incl. definitions.

The use of health indicators for health reporting

Today, various methods are used for health reporting:

- *Indicator-based health reporting*

On the basis of a well-defined indicator set, periodic health reporting is done to follow the indicators and trends. Changes of in the indicator level are analysed and described within the different chapters of periodic health reporting.

- *Indicator sets and their use for health reporting*

For writing health reports with the help of experts or for special topics (e.g. women’s health) a part of the indicators sets can probably be used, but usually not the complete indicator set. The advantage consists in the flexibility of the reporting, the disadvantage is the discontinuity of a frame for reporting such as „Health situation in South Eastern Europe”. However, within the Stability Pact a report based on

the Minimum Indicator Set for South East European countries was produced in 2003 (8) and can serve as a model for future similar reports aiming to support the decision-making process in the area and to track progress of these countries towards the goals of integration in the European Union.

• *Health targets, health indicators and health reporting*

WHO prefers health reporting on the basis of health targets. The advantage is the good tracking of the targets. A good example is the UK model or the „Healthy People" strategy of the United States (*www.health.gov/healthypeople*). The disadvantage lies in the time-consuming process of formulating common targets for several countries. Also the establishment of an indicator set with benchmarking criteria based on health targets takes a lot of time and is a difficult undertaking. Some targets may change in the course of the years and so you have to change your indicator set, too. Here WHO has made some experience. Thus the indicators of based on the new strategy HFA 21 are more „generic" and less „operational".

A review on health target settting in 18 European countries (13) demonstrated that Health for All strategy has influenced the health policy of almost all of the 18 countries.

EXERCISE: Health Indicators and Health Reporting

Task 1: After being familiar with the HFA software, students are asked to select a set of relevant indicators from this database and to prepare a report describing the situation from a certain country/region for the purpose of priority setting. Time: 120 minutes.

Task 2: Students are asked to search the Minimum Indicator Set (10) and make comparisons between SEE countries (e.g. in life expectancy at birth, infant mortality rate and SDR due to different causes) and try to find possible explanations.

Task 3: Review existing national data sources (available in your country) and look for available indicators also describing the local levels (e.g district, country, etc.) and make geographical comparisons. Commonly, reports or databases are reported by National Statistical Institutes/Bureaus and Institutes of Public Health.

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Databases for health indicators

WHO:

R1 Synopsis of HFA-Indicators at WHO-EURO in Copenhagen: *http://www.who.dk/cpa/pb9912e.htm*
R2 HFA Statistical Database at WHO-EURO: *http://www.who.dk/country/country.htm*
R3 Manual with Description of HFA-Indicators: *http://www.who.dk/country/HFAdbbook.pdf*
R4 Country Profiles Based on HFA-Indicators: *http://www.who.dk/country/country.htm*
R5 EUPHIN EAST Network Indicators: *http://www.euphin.dk/hfa/Phfa.asp*
R6 Indicators in the Healthy Cities Network (including questionnaire for data collection): *http://www.who.dk/healthy-cities/pdf/quest.pdf*

EU & OECD:

R7 European community Health Indicators (ECHI): Description of Project: *http://europa.eu.int/comm/dgs/health_consumer/library/tenders/call26_9_en.pdf*
R8 EUROSTAT Health Indicators as a Section of the Area „Population & Social Conditions": *http://europa.eu.int/comm/eurostat/Public/datashop/print-catalogue/EN?catalogue=Eurostat*
R9 OECD Statistical Portal / health statistics (Excel tables): *http://www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-statistics-194-5-no-no-no-194,FF.html*
R10 European community. Health Interview and Health examination survey databases *http://www.iph.fgov.be/hishes/*

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT **A Handbook for Teachers, Researchers and Health Professionals**	
Title	**Quality of Life: Concept and Measurement**
Module: 1.5	**ECTS (suggested): 0.50**
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Keywords	Quality of life, health related quality of life, measuring quality of life, SF – 36, Minnesota Questionnaire
Learning objectives	After completing this module students and public health professionals should have: • increased their understanding and knowledge of quality of life and measuring quality of life • get knowledge about differences among global, generic and specific instruments of quality of life • improve their skills in processing the Short Form, SF - 36
Abstract	Public workers and media use the term quality of life (QoL) related to the environment, physical and social: air pollution, soil and water pollution, living standards, and crime rates. The QoL term is used in philosophy literature, sociology, geography, health economics, medicine, psychology, and pharmaceutics industry. During the last years, quality of life is said to be „overwhelming" or „global", it is separated from the term health related quality of life. Measuring QoL is important because it is used for decision making especially about non-clinical aspects of disease, for improvement of the doctor – patient relationship, in discovering of functional and psychological limitations, in choosing the treatment in initial phase of disease, when the efficiency of a applied therapy is temperate (for example remedies just modify a disease). Measuring of quality of life and health related quality of life (HRQoL) could be: *unidimensional* and *multidimensional*. Measuring QoL and HRQoL can be: *global* and *specific (specific in relation to disease and in relation to medical treatment)*.
Teaching methods	Teaching methods include lectures, students individual work under the supervision of teacher and interactive methods such as small group discussion. Before introductory lecture, the small exercise could be organised as brainstorming ("What is quality of life for you?"), in order to increase students' motivation for learning and interest in the content of the module. After the introductory lecture

	students will work individually on comparison of dimensions among global, generic and specific instruments. Students should discuss in small groups what kinds of dimension of quality of life are in the general and specific instruments. They would also have opportunity to search through the Internet under the supervision of teacher in order to explore some of the web site concerning QoL and some bases of the quality of life questionnaire.
Specific recommendations for teachers	Teacher should be familiar with the process of SF-36 and Minnesota questionnaire analysis, especially standardization procedure and cultural adaptation.
Assessment of students	Multiple choice questionnaire.

QUALITY OF LIFE: CONCEPT AND MEASUREMENT

Zorica Terzić, Bojana Matejić

Definition of Quality of Life and Health Related Quality of Life

In everyday speech quality of life (QoL) suggests many outer conditions and personal features. Because of them an individual can feel satisfaction and dissatisfaction, he/she can plan keeping or changing the conditions one lives in. Public workers and media use the term related to the environment, physical and social: air pollution, soil and water pollution, living standards, and crime rates (1). The QoL term is used in philosophy literature, sociology, geography, health economics, medicine, psychology, and pharmaceutics industry.

During the last years, quality of life is said to be „overwhelming" or „global", it is separated from the term health related quality of life, so the consensus has been reached among experts on two important issues in the health related quality of life (HRQoL) field (2,3):

- it is recognized that the patient rather than a doctor or a nurse is the best source for obtaining HRQoL information.
- HRQoL is viewed as a multidimensional concept, which should include the four primary dimensions: *physical functioning*, encompassing self-care activities (eating, dressing), physical activities (walking, climbing stairs), and social activities (working, household, school); *physical symptoms* related to the disease or treatment (pain, diarrhea, neuropathy); *psychological functioning*, including emotional state and cognitive functioning; *social functioning* referred to the activities and association with friends, relatives and other acquaintances.

There are many definitions for QoL term, because of different approaches while considering it. Its meaning is differently explained and it depends on the user's age and position in social and political structure (4). QoL definition can be separated in general definitions, definitions specially related to health, and QoL definition specially related to disease (5) (Table 1).

Table 1. General definitions and definitions specifically related to health and disease

Author	**Global definitions**
Calman, 1984 (6)	The extent to which hopes and ambitions are matched by experience.
Ferrams and Powers, 1985 (7)	An individual' s perceptions of well-being that stem from satisfaction or dissatisfaction with dimensions of life that are important to the individual.
Grant et al, 1990 (8)	A personal statement of the positivity or negativity of attributes that characterizes one' s life.
Author	**Definitions specifically related to health**
Schipper, 1990 (9)	A pragmatic, day to day, functional representation of a patient' s physical, psychological, and social response to a disease and its treatment.
Cella and Tulsky, 1990 (10)	Patient's appraisal of and satisfaction with their current level of functioning as compared to what they perceive to be possible or ideal.
Gotay et al, 1992 (11)	A state of well-being which is a composite of two components: the ability to perform everyday activeties which reflect physical, psychological and social well-being, and patient satisfaction with levels of functioning and the control of disease and/or treatment related symptoms.
WHOQOL Group, 1993 (12)	Quality of life is defined as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationships to salient features of their environment.
Testa and Simpson, 1996 (2)	The physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person' s experiences, beliefs, expectations, and perceptions.
Author	**Definitions specifically related to disease**
Cella and Tulsky, 1990 (10)	HRQoL is more specific and more appropriate term than quality of life, because it refers to patients' assessment and satisfaction of their current level of functioning with it compared to what they consider to be possible or to be ideal.
Padila et al, 1998 (13)	The term HRQoL, connotes a personal, evaluative statement summarizing positive and negative attributes that characterize one' s psychological, physical, social, and spiritual well – being at a point in time when health, illness and treatment conditions are relevant.

Van Schayck, 1998 (14)	This concept, HRQoL is used to description of how patients experience their disease, actually how the severity of disease has possibly decreased the quality of life.
Patric and Erikson, 1998 (15)	HRQoL is the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment or policy.

Measuring Quality of Life

Measuring QoL is important because it is used for making decisions especially about non-clinical aspects of disease. It is also used for improvement of the doctor – patient relationship. It is important in discovering of functional and psychological limitations, in choosing the treatment in initial phase of disease, when the efficiency of applied therapy is temperate (for example remedies just modify a disease). It is also important when you chose therapies that are little different, when you chose among a few efficient, different, clinical therapies, when there are dilemmas in applied therapies because of toxins, costs as well as for supplying information about using resources (16,17).

Measuring of quality of life and health related quality of life could be unidimensional and multidimensional (18,19).

Unidimensional measuring refers to one dimension HRQoL. When they are used in clinical researches they can limit clinical information. They can show whether the treatment improves QoL, but they do not speak about the way of improvement. Multidimensional measuring is used in clinical researches. QoL assessment based on multidimension is important when there is a little information about the effects of a disease and/or treatment of a disease (20). Multidimensional measuring in the informal way points out which health intervention justifies invested money, but they can not be used for cost benefits analysis (21).

Also, measuring QoL and HRQoL can be: global and specific (specific in relation to disease, and in relation to medical treatment) (18,19).

Global measuring is used in general population to measure health status of population and to compare different health conditions or diseases. They are also focused on the basic human values such as emotional well-being and on the possibility of everyday functioning (2,22,23). Specific measuring is related to the domains, which are important for a disease; and for different states, that has priority for a patient. Most usually they are used in clinical researches of drugs or therapeutics' intervention (2).

If HRQoL is included in the clinical research, it has three important characteristics. First of all, the researchers, doctors, describe given conditions or a disease in terms, which are clinically important, and the patient can understand them easily. The second thing is that HRQoL domains can be independent predictor of the important clinical results – such as observing treatment, morbidity and mortality. These data insure precious consideration in history and prognoses of different states and diseases. The third thing, we can get data about the treatment, which determine individual daily functioning from the patient's point of view, what we can get or lose during the therapy. This can help a doctor to make decision to modify specific elements of therapy such as drugs, consultative health care, education of patients or help to the service (24,25). All these information should be added to the information that the doctor gets during physical examination, laboratory tests and medical history. However, measuring HRQoL is used in small number of clinical researches as a primary goal, although quality of life is often better prognostic indicator than factors connected to the disease or treatment (18).

Measuring QoL (and Health Related Quality of Life) can be done into three domains, that agrees with the health definition WHO: physical functioning (that includes symptoms, functional difficulties), psychological state (emotional and cognitive functions) and social interaction (work, daily activities, public relations). In case that measuring does not include one of these domains, HRQoL has negative assessment. However, number of dimensions can be much bigger (26).

Measuring QoL is not direct. An individual gives attributes (characteristics) that are measured and in the case of QoL that would be the level of physical functioning, mental health or social functioning (27). Measuring QoL must take into consideration subjective indicators (based on self-assessments). Subjective measuring QoL depends on personal preferences about determinants that are individual QoL. That is so called 'inner state' of QoL. There are also 'outer aspects' of QoL that are evaluated by self-report (obviously subjective) and by observing (obviously objective) (28). The subjective indicators represent all nonbiological factors that have influence on the recovery and they include patient's psychology, motivation and therapy acceptance, socioeconomic status, health protection, welfare work, personal and cultural convention and behavior (29). Indicators based on the patient are not in the indispensable correlation with the objective measures (for example: level of physical functioning) (30). They are more and more popular because of the importance of patient's satisfaction. It is also important what an individual feels in relation to what the statistics says that the individual should feel (31).

Subjectivity is the key element in the assessment and measuring QoL. 'Subjective experiences' are usually signified as potentially „soft data" or „soft science" contrary to the objective data. That are represented as „hard data" or „hard science" (17,32).

The instruments for measuring Quality of Life

The instruments for measuring QoL are multidimensional, complex and indirect. Multidimensionality demands combination of different terms and domains. Complexity means simple questions or sums (they refer to the measured term) that are grouped into subscales, and the subscales form wider scales. Casual effects that appear indirectly are connected to the variability, which can be in relation to the questionnaire respondents and the period needed for questioning (33).

The instruments for measuring quality of life can be *global***,** *generic* and *disease specific*.

Global measures (instruments) are designed to measure QoL in the most comprehensive or overall manner. This may be a single question that asks the respondent to rate his/her overall QoL or this may be an instrument such as the Flanagan Quality of Life Scale that asks people to rate their satisfaction in 15 domains of life (34).

Generic measures (instruments) have much in common with global measures, but they are designed primarily for description. They are used in general population for the assessment of health status, different conditions or diseases. Usually, they are not specific for a particular disease or vulnerable population of patients and they are much more useful in general health researches, comparisons of different diseases and several studies. General instruments include large number of quality of life dimensions but at first place physical, mental and social dimension (2,34).

Deficiency of generic instruments is (35,36,37):

– they are unable to identify condition – specific aspects of disease that are significant for the measurement QoL
– if the data is necessary for major number of conditions, the instruments would have to be of enormous length
– an addition to specific instruments for a disease is needed to detect important clinical changes

Table 2. Generic instruments for measuring QoL

GENERIC INSTRUMENTS FOR MEASURING QOL		AUTHOR, YEAR
Quality of Well-Being Scale	QWBS	Fanshel & Bush, 1976
Sicknes Impact Profile	SIP	Gilson & Bergner, 1976 (revidirana 1981)
McMaster Health Index Questionnaire	MHIQ	Chambers, 1976
Nottingham Health Profile	NHP	Hunt et al, 1985
Medical Outcomes Study (MOS) Short Form 36 – item	MOS – SF - 36	Ware, 1992
Medical Outcomes Study (MOS) Short Form 12 – item	MOS – SF - 12	Ware, 1994
Assessment of Quality of Life	AQoL	Hawthorne & Richardson
Comprehensive Assessment and Referral Evaluation	CARE	Fretwell
EQ – 5D	EQ – 5D	EuroQol Group, 1991
Dartmouth Coop Function Charts	COOP - C	Dartmouth COOP Project, 1987
Visual Analogue Scale	VAS	Fryed, 1923
Functional Limitations Profile	FLP	Patrick
General Health Questionnaire	GHQ	Goldberg&Williams, 1978
Health and Daily Living Form	HDL	Moos
Health Measurement Questionnaire	HMQ	Gudex & Kind
Healthy People 2000 years of Healthy Life	HP - 2000	Erickson, 2000
Health Status Questionnaire 2.0	HSQ	RAND Corporation, 1976
Quality of Life Questionnaire-Evans	QLQ - E	Evans & Cope
Symptom Checklist-90-Revised (SCL-90-R)	CARE	Derogatis
Schedule for the Evaluation of Individual Quality of Life	SEIQoL	O'Boyle & McGee, 1994
WHO Quality of Life Assessment	WHOQOL	WHOQOL, 1993 Group, WHO

Disease specific instruments are orientated on the domains most relevant to the disease, condition or characteristics of patients in whom the condition is most prevalent. They use of a particular treatment or clinical trial and they may be called „*treatment specific*" or „*trial specific*", apropos by one name „*situation – specific*" (38).

Specific instruments are needed for their homogeneity/brevity, and to ensure sensitivity for sometimes small, but clinically significant changes in health state and intensity of a disease (31). The recommendation is to use the combination of generic and specific instruments in the case when an overall QoL instruments are not satisfied for specific diseases (31).

Quality of Life Instruments Database (QOLID) is made in the joined project of the French Mapi Institute and the Italian National Institute for Cancer. This base contains 1000 globals, generic and specific questionnaires. Generic measuring instruments are represented in the Table 2. Some of the specific measuring instruments selected on the number of performed cultural adaptations are represented in the Table 3 (39,40).

Table 3. Specific instruments for measuring QoL

SPECIFIC INSTRUMENTS FOR MEASURING QOL		
Cardiovascular diseases	Minnesota Living with Heart Failure Questionnaire	MLHF
	Seattle Angina Questionnaire	SAQ
	Angina Battery	
Gastroenterology	Inflamatory Bowel Disease Questionnaire	IBD QoL
	Personal Health Survey (Hepatitis)	
	2 – item Chromic Idiopathic Constipation	CIS 2
	Irritable Bowel Syndrome QoL	IBSQOL Battery
Respiratory diseases	St George's Hospital Respiratory Questionnaire	SGRQ
	Chronic Bronchitis Questionnaire	CHROBRON
	Adult Asthma QoL Questionnaire	AQLQ
Rheumatology	Osteoporosis and QoL	Ostop battery
	Osteoporosis Targeted – QoL Questionnaire	OPTQOL
	Health Assessment Questionnaire	HAQ
Endocrinology	Impact of Weight questionnaire	IWQOL
Diabetes	Impact Measurement Scale	DIMS
	Experience of Treatment benefits and Barriers	ETBB
	Diabetic Foot Ulcer Scale	DFUS

Neurology	Quality of Life for patients with newly diagnosed	NEWQOL
	Quality of Life in Epilepsy	QOLI-3
	Side – Effects and Life Satisfaction Inventory	SEALS
	Functional Assessment of Multiple Sclerosis	FAMS
Psychiatry	Psychological General Well – Being Index	PGWBI
	Drug Attitude Inventory	DAI
	Wisconsin Quality of Life Index	WQLI
Sleep	Jebnkins Sleep Questionnaire	
	MOS Sleep Module Questionnaire	MOS – SLEEP
	MOS Sleep Questionnaire (short version: 6 items)	
Sexuality	Erectile Dysfunction Quality of Life Questionnaire	ED
	MOS Sexual Function	MOS – SEXUAL
	Sexual Function Index (male)	
Gynecology	Women's Health Questionnaire	WHQ
	Menopause Quality of Life Questionnaire	MEQOL
	Quality of Life in Menopause	MENO
Pediatric	Pediatric Asthma QoL questionnaire	PAQ
	Pediatric Rhinoconjunctivitis QoL Questionnaire	RCQLQ
Dermatology	Hair Growth Questionnaire	
	Infant's Eczema Life Quality Index	IELQI
	Children's Dermatology Life Quality Index	CDLQI
Oncology	Quality of Life Index	QLI – OSTOMY
	Europen Organization for Research and Treatment of Cancer's Quality of Life Questionnaire 30	EORTC – QLQ – C30
	Europen Organization for Research and Treatment of Cancer's Quality of Life Questionnaire 33	EORTC – QLQ – C33

Urology	Incontinence QoL Questionnaire	COAT
	Benign Prostatic Hyperplasia	UROLIFE
	Benign Prostatic Post – Operative Pain Hypertrophy Impact Index	BPHII
Pain	Migraine Specific Quality of Life Questionnaire	MIG16
	Pain Management Satisfaction Questionnaire	POP2
	Post – Operative Pain	POP
Aids	MOS - HIV	SF – 30
	Citomegalovirus Specific Questionnaire	CMV

Generic questionnaire SF – 36

The example of generic instruments of quality of life is SF – 36. The SF – 36 was developed in the United States in the late 1980s as part of the Medical Outcomes Study (MOS), a longitudinal investigation of the self-reported health status of patients with different chronic conditions. The questionnaire enables an acceptable, psychometrically correct and efficient way to measure the quality of life from the patient's point of view through answers to questions from a standardized questionnaire. The SF – 36 questionnaire was constructed to measure eight most important health dimensions by using eight groups of questions. The groups include two to ten questions and each of them offers several responses in the form of two levels, three levels and five level scales (41).

The SF – 36 questionnaire consists of 36 questions, and 35 questions of them are grouped in eight dimensions: physical functioning, role – physical, bodily pain, general health, vitality, social functioning, and role – emotional and mental health. One question is not included in these eight dimensions and it is observed independently. It concerns health change compared to the status one year ago, is current health better, whether it is the same or worse, unlike all other questions that refer to the period of the previous four weeks (41).

Physical functioning dimension has 10 questions, and it refers to the possibility of practicing different physical activities during a typical day and the level of limits in those activities provoke by current health status. These activities are: vigorous activities (running, lifting heavy objects, participating in strenuous sports), moderate activities (moving a table, pushing a vacuum

cleaner, bowling or playing golf), lifting or carrying things, climbing stairs, bending, kneeling or stooping, possibility of walking and self-care (bathing or dressing).

Physical Role Dimension comprises four questions. The questions refer to problems with work or other regular daily activities as a result of your physical health.

Dimension Body Pain is based on two questions: one question concerns the existence of body pain and its intensity during the past 4 weeks, and the other question concerns interference of pain with normal work outside the house and housework.

Dimension General Health has five questions. The questions refer to the assessment of current health, and the respondent's opinion about the accuracy of certain claims about resistance to illness, health prognosis and opinion about present health.

Dimension Vitality consists of four questions, that refer to how the patients felt and how successful they were in doing things during the past 4 weeks and how much of the time they feel like that (all the time, most of the time, a good bit of the time, some of the time, a little of the time, none of the time) during that 4 weeks. The questions include the exhaustion, tiredness, feeling that they are full of life and the assessment of their energy.

Dimension social functioning consists of two questions, the one question concerns on interfered physical health or emotional problems with usual social activities with family, friends, neighbors or other during the past 4 weeks, and the other question refers to the period of limitation, i.e. the negative effect of damaged physical or emotional health on social activities, such as visiting with friends or relatives during the past 4 weeks.

Dimension Role – Emotional represents three questions concerns on problems with work or other regular daily activities as a result of any emotional problems, such as feeling depressed or anxious in the past four weeks.

Dimension mental health comprises five questions that refer to the presence of anxiety, sadness, peace, depression and happiness and how long they were feeling like that.

Standardization Procedure of SF – 36

The standardization and scoring are basic procedures in the interpretation of the SF – 36 questionnaire whose comparison of results among studies

makes possible. There are two reasons for conveying standardization. First, to enable scoring with same reliability and validity as reported in Medical Outcomes Study (MOS) publications. The second reason is enabling the comparison of results between all studies that are using the standardization content and standards for scoring (41).

Scoring questionnaire SF – 36 is conducted through several steps: entering data, recording out-of-range item values as missing, reverse scoring and/or recalibrate scores for 10 items, recording missing item responses with mean substitution (where warranted), computing raw scale scores, transformation of raw scale scores to 0 – 100 scale, performing scoring checks (41).

Specific questionnaire – The Minnesota Living with Heart Failure (MLHF)

The example of the specific instrument is Minnesota Living Heart Failure (MLHF). The MLHF questionnaire was arised for need that through self-assessment evaluated the answer for applied therapy in the case of heart failure. Several criteria were used for developing the questionnaire MLHF (42). The first criterion is used for the questionnaire which should measure what it is defined to. The second one: the questionnaire should be applied in clinical practice. The third one: the numeric values are assigned to responses. The fourth one: the score is reliable during the stable clinical condition, so that it can identify the changes during interventions. There is also the fifth one: the questionnaire is valid measure of the quality of life. In relation with the other specific instruments which measure QoL of patients with heart failure, its advantages are (43):

- It includes optimal number of questions about physical activities, which at the same time can demonstrate even the different degree of limitations during physical activity.
- At the same time, it also follows dispnea and fatigue during the specific activities, as well the other signs and symptoms of a disease.
- Patient's point of view is also included in the score about the importance of different symptoms.
- The only specific instrument which has represented itself as being reliable in double blind clinical trials.

The questionnaire MLHF consists of two parts; first one is instruction for use and intended for the researchers, and second one is the questionnaire itself.

The instructions are given to the researcher to help him interview patients and how he can process the results. The questionnaire should be self-administered or researcher may read it directly to the patient, before any medical intervention, so that we can get whole impression about patients' health condition before applied medical intervention. The patient should have enough time to fulfill questionnaire and he should not be disturbed. Before, the participants started responding, the instructions should be given: you should read the introductory paragraph at the top of the questionnaire and explain the way the questionnaire should be completed. You should emphasize that all the questions are about the changes caused by heart failure.

The questionnaire itself consists of the introductory paragraph and 21 questions with answers. Introductory paragraph emphasizes that all the changes caused by heart failure happened during the last month. The questions refer to present disease symptoms (short of breath, fatigue, outworn, loss of energy), signs of heart failure (swelling ankles, legs), limitations caused by disease (difficulties during climbing stairs, working around the house, going away from house, difficulties in earning for living, in relations with family and friends, difficulties while making recreation, pastimes, sports and hobbies, sleeping and sexual problems, taking rest during the day, eating less). It also includes questions about staying in hospital, medical car costs, medications' side effects as well as emotional problems (their feeling that they are burden to the family or friends, loosing self-control in their lives, presence of worriness, depression, and difficulties to concentrate or remember things).

The answers are represented as six grade scale from „no" (0) over very little (1) to very much (5). Lower values are the signs of better life quality.

The Steps in the Cultural Adaptation: an Example of Serbian Minnesota Questionnaire

The cultural adaptation demands use of a proper language so that the translated questionnaire should be conceptual equivalent to the original and clear and understandable for a patient.

The conceptual equivalence means that the translation should faithfully reflect the (items) notions investigated in the questionnaire, without repeated interpretation the original formulation of the questionnaire and without limitation of original means. During this, we face several problems and these are ambiguous words in the questionnaire and impossible translation for a certain English term. If a formulation in the original questionnaire is ambiguous, than Mapi Research Institute solves that ambiguousity by asking the author for cla-

rifications, in order to know exactly what is the concept investigated in the original and consequently in the translations. If there is not equivalent in the target language (in this case – Serbian) for an English term in the original questionnaire then the word closest in meaning to the original word should be chosen in the target language. In the case that the English term cannot be replaced by 1 word only, than is better to use 2 or 3 words instead, that could cover the meaning of the original term.

The comprehension of the language used means to use simple, clear and easily understandable words, expressions and sentence structures. Also, the recommendation is to use the expressions, which are used in everyday language. Actually it is better to use expressions from everyday language than the expressions which could be found in the books and newspapers. This recommendation should be achieved, because it deals with the population of patients with high level of education (university educated). Also, if there are two expressions, which are easily understandable, we should use the expression more frequently used in everyday speech.

On respecting these rules, in some cases it happens that grammatically incorrect language structure is used. It might happen, that grammatically correct expressions need request complex and massive structure, which are never used in everyday conversation. Than, we can use expressions, which are very often used in conversation, but they are not completely grammatically correct.

Also, it's possible that a literal translation of the original questionnaire refers to the same concept as in the original, and at the same time it is clear and easily understandable. Such literal translation should be kept.

The process of cultural adaptation (translation) is implemented through three steps: ***forward translation, backward translation*** *and* ***patient testing.***

Forward translation

Forward translation consists of a few phases: engagement of two profession translators, making reconcile – the first intermediary version (forward translation), making the report for Mapi Research Institute and making the final first intermediary version.

The native language of the engaged professional translators must be Serbian and their English must be very good, too. They are independent in translating instruction for use and the questionnaire (instruction for filling,

original questions and responses) and they produce two version of forward translation (every translator gives an independent forward translation).

The reconciled – first intermediary version is created during the meeting of both translators and the local project manager (author of this paper). The translators compare their translations among themselves and compare them with the original questionnaire. The aim is to produce a conceptually equivalent translation of the original questionnaire and the language used which should be colloquial and easily understandable.

The project manager makes the report for Mapi Institute for each question in English. Also, the project manager explains translation problems, difficulties in translation, offers and accepts solutions and options of the first reconciled intermediary version of forward translation, explaining translation problems, disagreements of the translators in the translation, offered and accepted solutions.

The final reconciled, intermediary version of the translation arises after the Mapi Institute has analyzed the report and after their suggestions have been loaded into the first intermediary version.

Backward translation

The forward translation implies a few phases: the engagement of the professional translator, making backward translation, loading the changes into the first intermediary version, making the report for Mapi Institute and making the second intermediary version.

The native language of the engaged professional translator must be English and his Serbian must be very good, too. His task is to translate the first reconciled intermediary version of forward translation into English as more literal as possible. The translator must not see the original English questionnaire before he begins to translate.

Backward translation emphasizes disagreements and differences (that exist) between the first intermedialy version and the original questionnaire. This is achieved by translating the backward translation and the original questionnaire. The aim of the meeting between project manager and translator is: to go carefully though the whole questionnaire, question by question, sentence by sentence and make comparison of three documents (the backward translation into English, the English original questionnaire and the first intermediary version for each single part of the questionnaire).

The differences that the project manager and translator of backward

translation should notice when making the comparasion should be: faulty backward translation, faulty forward translation and structural differences between backtranslation and the original questionnaire.

The revision of the whole questionnaire was made at the meeting between the project manager and the translator. Also, project manager establishes the changes that should be made to the first intermediary version. The first intermediary version with the report of modification after backtranslation, and the backtranslation itself are sent to the Mapi Institute. The report should mention all the discrepancies between the backtranslation and the English original as well as the explanations of all fond differences caused by faulty backward translation or faulty forward translation or structural differences between backtranslation and the original questionnaire. Also, the report should mention the explanation of the changes that have or have not been brought in the first intermediary version.

Mapi Institute reviews the backtranslation and report. All disagreements with respect to the original questionnaire are discussed with the local project manager. The second intermediary target (Serbian) version arises after agreement on all the changes that were made into the first intermediary version.

Patient Testing or Cognitive Debriefing

This step, Patient Testing, includes: testing of the second intermediary version of the questionnaire, making reports for Mapi Institute, acceptance of the second intermediary version or making the third intermediary version that would be more clear than the previous one and more acceptable for all persons who use it. Mapi Institute should engage translators whose native language is Serbian and their task is to make the final version of the questionnaire.

The aim of the patient testing is: to test the comprehension and acceptability of the second intermediary version; to identify questions that are problematic as well as the reason for it; and to write down possible suggestions for understanding the formulation of questions.

The second intermediary version questionnaire is tested on a panel discussion, face to face with 5 patients who are suffering from heart failure. The idea was to choose five patients who would be representatives of patient population in our country. There are following criteria that are recommended while choosing patients: their education, profession and age.

When we speak about *education*, it is better that patients are with lower

level of education. Previous experiences have shown that people with a high level of education (professors, teachers, scientists, and doctors) never have difficulties in understanding while testing the questionnaire. It is preferable to have patients from several *professional groups*, but this should not be in contradiction with their education.

The role of the project manager is to discover all misunderstanding or misinterpretations and to identify words or wordings that may be inappropriate and to write down. For the project manager is also important to express patient's feeling when answering some questions (face expression shows agreement or disagreement).

Throughout panel discussion project manager asks questions to the respondents about their general impression about questionnaire: is it globally clear, easy to understand, easy to answer, is it too long, is it adapted for the condition, are the instructions clear?

After that, together with patients, he goes through to whole questionnaire, question by question and checks:

- Are the questions difficult for understanding? If so, why?
- Are the offered answers clear and consequent with the questions?
- Is the primary concept of questions interpreted correctly? Is there ambiguous formulation that would make more than one possible interpretation?
- Is the language used easy to understand and is the language used as daily speech?

Then the project manager makes one independent report of the panel discussion. He has to explain suggested changes that project manager finds to be relevant and the changes he suggested to be kept.

After the report has been examined and after discussion of patient testing results with Mapi Institute, the third intermediary version of the questionnaire is made by integration of all changes into next intermediary version. It is also possible to keep the second intermediary version if there are not any significant changes.

Mapi Institute engaged two local translators whose native language is Serbian and their English is also very good, so they can translate the third (or second) intermediary version (Serbian) of questionnaire in English. During the meeting of these two translators they compare translations to the original.

Changes that local translators suggest are discussed with project manager. The final version of the questionnaire is created and it is based on the results of this discussion.

EXERCISE: Measuring Quality of Life

The purposes of the exercises are to provide students with basic information about quality of life and measuring quality of life.

Task 1: Comparison of dimensions between generic and specific instruments

Students work individually. The students are given the generic questionnaires SF – 36, SF – 12, SF – 8 and specific Minnesota Living with Heart Failure questionnaire. They should notice the differences between these four questionnaires and discuss about dimensions from these questionnaires. Some of students will report what they understand from comparison. Time: 90 min.

The questionnaires SF – 36, SF – 12 and SF – 8 are available from http:// www.qualitymetric.com

The specific Minnesota Living with Heart Failure questionnaire is given below in this task.

Task 2: Filling in SF – 36

The students fill in SF – 36 and with instruction for scoring: they are getting their scores of quality of life. They can compare their score with national's standards. The instruction for scoring SF – 36 is available from http:// www.qualitymetric.com. The national's standards are given in the Table 4. Time: 180 min.

LIVING WITH HEART FAILURE QUESTIONNAIRE

Instructions for Use

1. Patients should respond to the questionnaire prior to other assessments and interactions that may bias responses. You may tell the patient that you would like to get his or her opinion before doing other medical assessments.
2. Ample, uninterrupted time should be provided for the patient to complete the questionnaire.
3. The following instructions should be given to the patient each time the questionnaire is completed.
    a. Read the introductory paragraph at the top of the questionnaire to the patient.

b. Read the first question to the patient - „Did your heart failure prevent you from living as you wanted during the past month by causing swelling in your ankles or legs"? Tell the patient, „If you did not have any ankle or leg swelling during the past month you should circle the zero after this question to indicate that swelling was not a problem during the past month". Explain to the patient that if he or she did have swelling that was caused by a sprained ankle or some other cause that was definitely not related to heart failure he or she should also circle the zero. Tell the patient, „If you are not sure why you had the swelling or think it was related to your heart condition, then rate how much the swelling prevented you from doing things you wanted to do and from feeling the way you would like to feel". In other words, how bothersome was the swelling? Show the patient how to use the 1 to 5 scale to indicate how much the swelling affected his or her life during the past month - from very little to very much.

4. Let the patient read and respond to the other questions. The entire questionnaire may be read directly to the patient if one is careful not to influence responses by verbal or physical cues.

5. Check to make sure the patient has responded to each question and that there is only one answer clearly marked for each question. If a patient elects not to answer a specific question(s) indicate so on the questionnaire.

6. Score the questionnaire by summating the responses to all 21 questions. In addition, physical (items 2, 3, 4, 5, 6, 7, 12 and 13) and emotional (items 17, 18, 19, 20, and 21) dimensions of the questionnaire have been identified by factor analysis, and may be examined to further characterize the effect of heart failure on a patient's life.

LIVING WITH HEART FAILURE QUESTIONNAIRE

These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (No) and go on to the next item. If an item does apply to you, then circle the number rating how much it prevented you from living as you wanted.

Did your heart failure prevent you from living as you wanted during the last month by:

	No	Very little				Very much
1. Causing swelling in your ankles, legs, etc.?	0	1	2	3	4	5
2. Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. Making your working around the house or yard difficult?	0	1	2	3	4	5
5. Making your going places away from home difficult?	0	1	2	3	4	5
6. Making your sleeping well at night difficult?	0	1	2	3	4	5
7. Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. Making your working to earn a living difficult?	0	1	2	3	4	5
9. Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. Making your sexual activities difficult?	0	1	2	3	4	5
11. Making you eat less of the foods you like?	0	1	2	3	4	5
12. Making you short of breath?	0	1	2	3	4	5
13. Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. Making you stay in a hospital?	0	1	2	3	4	5
15. Costing you money for medical care?	0	1	2	3	4	5
16. Giving you side effects from medications?	0	1	2	3	4	5
17. Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. Making you worry?	0	1	2	3	4	5
20. Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. Making you feel depressed?	0	1	2	3	4	5

Table 4. Item means of dimensions of SF – 36 by country

Item	CR	DE	FR	GE	IT	NE	NO	SP	UK
Physical Functioning (PF)									
PF01	2.04	2.36	2.29	2.26	2.38	2.17	2.16	2.43	2.25
PF02	2.34	2.73	2.59	2.62	2.75	2.63	2.75	2.74	2.58
PF03	2.40	2.76	2.64	2.60	2.72	2.58	2.72	2.78	2.61
PF04	2.28	2.81	2.78	2.72	2.78	2.63	2.75	2.81	2.63
PF05	2.48	2.79	2.76	2.66	2.78	2.67	2.75	2.77	2.71
PF06	2.29	2.81	2.73	2.67	2.80	2.66	2.84	2.82	2.65
PF07	2.36	2.89	2.88	2.75	2.90	2.80	2.90	2.86	2.76
PF08	2.51	2.88	2.84	2.81	2.89	2.81	2.92	2.86	2.80
PF09	2.62	2.91	2.91	2.84	2.93	2.86	2.94	2.90	2.88
PF10	2.66	2.91	2.92	2.87	2.95	2.93	2.95	2.93	2.92
Role - Physical (RP)									
RP1	1.67	1.79	1.78	1.79	1.80	1.73	1.72	1.85	1.78
RP2	1.60	1.89	1.90	1.83	1.86	1.81	1.84	1.87	1.85
RP3	1.65	1.84	1.84	1.82	1.83	1.77	1.81	1.87	1.80
RP4	1.60	1.85	1.82	1.81	1.82	1.75	1.80	1.87	1.80
General Health (GH)									
GH1	2.68	3.53	3.36	3.03	3.06	3.28	3.57	3.08	3.50
GH2	3.60	4.13	3.82	3.56	3.52	3.74	4.32	4.03	3.91
GH3	3.26	3.90	3.66	3.45	3.91	3.85	4.01	3.75	3.69
GH4	3.19	4.00	3.65	3.77	3.78	3.71	3.86	3.90	3.61
GH5	2.95	4.43	4.27	4.17	4.28	4.36	4.49	4.35	4.35
Vitality (VT)									
VT1	3.41	4.34	4.01	3.96	3.89	4.55	3.61	4.29	4.09
VT2	3.38	4.04	3.43	3.99	4.12	4.26	3.45	4.16	3.95
VT3	3.90	5.14	4.70	4.47	4.90	4.79	4.50	4.81	4.50
VT4	3.68	4.55	4.07	3.99	4.02	4.19	4.51	4.50	4.17
Role - Emotional (RE)									
RE1	1.76	1.81	1.79	1.85	1.77	1.79	1.75	1.89	1.85
RE2	1.70	1.91	1.90	1.91	1.84	1.84	1.88	1.90	1.89
RE3	1.71	1.90	1.82	1.89	1.76	1.84	1.84	1.90	1.89
Mental Health (MH)									
MH1	4.09	4.48	3.83	4.31	4.03	4.44	4.31	4.18	4.17
MH2	4.76	4.55	4.02	4.16	4.01	4.67	3.97	4.54	4.59
MH3	3.47	4.48	4.23	4.62	4.37	4.76	5.54	4.53	5.29
MH4	4.49	5.77	5.18	5.18	5.10	5.37	5.27	5.28	5.30
MH5	3.61	5.25	4.99	4.98	4.74	5.00	5.24	5.00	4.94

Abbreviations: **CR** = Croatia; **DE** = Denmark; **FR** = France; **GE** = Germany; **IT** = Italy; **NE** = Netherlands; **NO** = Norway; **SP** = Spain; **UK** = United Kingdom

Source: Vuletic G, Babic-Banaszak A and Juresa V. Health-Related Quality of Life (HRQoL) Assessment in the Croation Population using the SF – 36. Quality of Life Newsletter 2002; 29: 7.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Disability-Adjusted Life Years: A Method for the Analysis of the Burden of Disease**
Module: 1.6	**ECTS (suggested): 0.25**
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Keywords	Population health status, global burden of disease, premature death, disability
Learning objectives	At the end of this course, students should: • identify the basic concepts of the global burden of disease assessment; • be able to describe the factors influencing the calculation of DALYs (age-weights, discount rate, severity of disability); and • be able to describe and compare the health status of population based on global burden of disease methodology.
Abstract	This course covers the following topics: Definitions and basic concepts; Health status assessment by use of DALY; Exercise.
Teaching methods	Teaching methods include lecture, interactive presentation of key concepts, overheads or PowerPoint presentation. Exercise will be solved in small groups (4-5 persons) and an overhead will be presented by each group with their comments.
Specific recommendations for teacher	It is recommended that the module will be organized within 0.25 ECTS credits, out of which 3 hours will be done under supervision (lecture and exercise solving), and the rest is individual student's work. Examples of studies performed in their own countries should be used.
Assessment of students	1. Reports presented by each group are considered as assessment. 2. An essay on the types of interventions required in own countries based on information from WHO sites or studies performed at national/local level.

DISABILITY-ADJUSTED LIFE YEARS: A METHOD FOR THE ANALYSIS OF THE BURDEN OF DISEASE

Adriana Galan

Definitions and basic concepts

Generally, statistics describing the health status of population suffer some limitations, reducing their practical value for the decision-making process:

- first, the data are incomplete and fragmented. Even if for example, the mortality data are available, they cannot describe the impact on health status of the different diseases or non-fatal disorders (like dementia or blindness for instance);
- second, the estimates of death cases of different diseases can be inflated by epidemiologists acting as advocates for a target population, in order to obtain more resources;
- last, but not the least, traditional statistics don't allow decision-makers to compare the relative cost-effectiveness of different interventions (1).

This is why a new approach called the „Global Burden of Disease" was proposed, trying to solve the above-mentioned problems and having three explicit goals:

- to include the non-fatal conditions into the health status evaluation;
- to produce objective, independent and demographically credible evaluation of the burden of disease;
- to convert the burden of disease into a general currency, in order to calculate the cost-effectiveness of different interventions.

In order to integrate both the impact of premature death and disability into one single currency, time measurement was considered to be an important integrative factor: time (years) lost by premature death and time (years) lived with disability. A standardized indicator called **D**isability **A**djusted **L**ife **Y**ear (DALY) was proposed for the measurement of the global burden of disease. DALY represents the years of life lost due to premature death and years lived

with disability of a specified degree of severity and duration. Therefore, one DALY represents one year of healthy life lost.

Premature death is defined as one that occurs before the age to which a dying person would have expected to survive, if this person would belong to a standardized population pattern having the longest life expectancy at birth in the world, meaning the female population of Japan.

To calculate the total number of DALY for a certain condition in a population, Years of Life Lost (YLL) and Years Lived with Disability (YLD) of a certain degree of severity and duration must be estimated. Then, these estimates must be summed up. For instance, to calculate DALY due to traffic accidents for one year, the total number of years of life lost due to fatal traffic accidents and the total number of years lived with disability by the accidents survivors must be summarized.

Even if to quantify the burden of disease looks like a simple exercise, a society must define first its ideal health status, considered to be the reference one. This means to find the answer for fundamental basic questions:

- *What would be the ideal life expectancy*? *Are all people equal*?

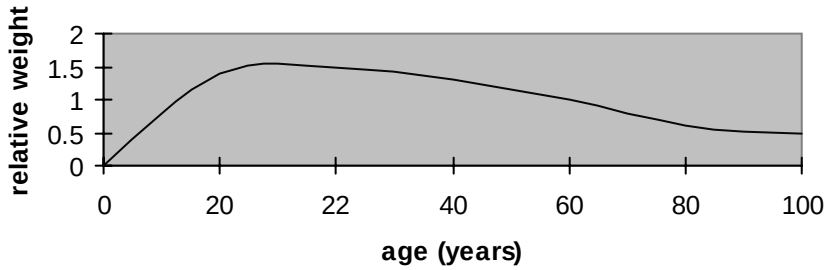
The researchers must decide on the expected number of years a person of a certain age would live in a reference (ideal) population.

DALY is based on egalitarian principle. Only age and gender were considered for calculating the burden of disease, these two characteristics not being directly related to health. There were not considered characteristics such as: socioeconomic level, ethnicity or level of education. According to these principles, for calculating DALY a standard life-table was used for all populations, life expectancy at birth being 82.5 years for females and 80 years for males.

- *Are the healthy life years more precious for young adults than for infants or elderly?*

Generally, if one should choose between saving a life of a 2 years old child and of a 22 years old person, most people would prefer the 22 years old person. This is due to the fact that an adult plays a more important role in family, community and society. This was the reason for the researchers to include an age-weighting to calculate DALY. It was assumed that the relative value of one life year rapidly increases from zero (at birth) to a peak around 20 years of age, decreasing after this age but less sharply (see Figure 1).

Figure 1. Relative Value of one year lived at different ages, included into DALY



- Is a healthy life year more important now for a society than 30 years later?

It is very likely that a person would prefer to receive today 100 € rather than after one year. Like the depreciation of one EURO over time, it seems that the value of healthy life is depreciating over time. Usually it is preferred to experience a healthy year of life now rather than some years thereafter, even if this opinion has initiated lots of debates among economists, experts in medical ethics and public health decision-makers.

Despite these debates, the researchers decided to discount the future years of life, e.g. by 3% per year. Discounting looks like an exponentially decreasing function. Due to the fact that the discount is significant, the researchers are usually publishing also DALY calculated without the discount factor.

Discounting future health reduces the value of interventions having a long-term impact – for example the impact of vaccination against hepatitis B, which can prevent thousands of future cases of liver cancer, however many years later.

- How can one compare YLL with YLD?

While death can be easily defined, the definition of disability is more complicated. Usually, there are two methods used to evaluate the social preferences of certain health states.

Both methods involve peoples' judgement on the compromise between quantity (length) and quality of life. This can be expressed as a compromise for time (how many years lived with disability would be changed for a fixed period of perfect health) or a compromise between persons (the choice between saving one year of life for 1000 healthy people or half a year of life for 2000 persons having health problems). A protocol based on person trade-off method was established. This was possible due to a formal exercise organized by

WHO in 1995 (2), where worldwide health professionals have participated. The severity for 22 disability conditions was weighted between 0 (perfect health) and 1 (equivalent of death) (Table 1). These weights for the 22 disability conditions were grouped into 7 classes.

Table 1. Severity of disability: disability classes and weights set for 22 indicator conditions

Disability class	Severity weights	Indicator conditions
1	0.00 – 0.02	Vitiligo on face, weight-for-height less than 2 standard deviations
2	0.02 – 0.12	Watery diarrhea, severe sore throat, severe anemia
3	0.12 – 0.24	Radius fracture in a stiff cast, infertility, erectile dysfunction, rheumatoid arthritis, angina
4	0.24 – 0.36	Below-the-knee amputation, deafness
5	0.36 – 0.50	Rectovaginal fistula, mild mental retardation, Down syndrome
6	0.50 – 0.70	Unipolar major depression, blindness, paraplegia
7	0.70 – 1.00	Active psychosis, dementia, severe migraine, quadriplegia

Source: WHO. Available at http:\\www.who.int.

To assess the impact of varying these social choices on the final measures of burden of disease, the researchers have calculated DALY with alternative age-weighting and discount rates, and with alternative methods for weighting the severity of disability.

Generally, the ranking of diseases and the distribution of burden by cause groups are substantially not affected by age-weighting and slightly affected by the method for weighting disability. By contrast, changes of the discount rates may have a more significant effect on overall results. The most significant effect of changing the discount rate and age weights is to reduce the relative importance of psychiatric conditions.

However, the accuracy of basic epidemiological data from which DALY is calculated will influence the final results much more than any of the above-mentioned weights. We can conclude that efforts should be firstly invested in improving the basic epidemiological data.

Health Status Assessment by use of DALY

A WHO study on the world burden of diseases showed that the top 10 causes of disease burden are responsible for 46% of all DALY (see Table 2). It was also shown that five of the top 10 causes of DALY primarily affect children under 5 years of age. Two of the top 10 causes (malaria and HIV) predominantly affect poor populations. These 7 causes are all part of infectious diseases, perinatal conditions and nutritional disorders, representing WHO priorities. The remaining 3 causes (unipolar major depression, ischemic heart disease and cerebrovascular disease) are chronic diseases.

Rankings based on DALY differ substantially from rankings based on the number of deaths. The importance of major depression worldwide, even if it generates only few deaths, was one of the key findings of this study.

The weight of certain causes of total DALY differs significantly if the results are analyzed by geographical distribution. For example, in sub-Saharan Africa, HIV accounted for 20% of the burden of disease in the region; malaria, tuberculosis and vaccine-preventable childhood diseases were responsible for another 20%. On the other hand, although road traffic accidents, falls and self-inflicted injuries account for 6.7% of total DALYs, their prevention was not a key issue of the public health policy in developing countries.

If we analyze the burden of disease attributable to different risk factors, we notice that in 1990, malnutrition accounted for almost 6 million deaths (11.7% overall) and 220 million DALYs (15.9% overall); tobacco use accounted for 3 million deaths and 36 million DALYs (see Table 3).

Similar studies were performed in USA. In 1996, 34.5 million DALYs were lost: 18.5 million for men and 16 million for women. It's worthwhile to notice that the major causes of DALYs differ significantly between developed countries and the rest of the world. E.g. in USA the 9 of the top 10 causes of DALYs include injuries and non-communicable diseases.

Table 2. Leading Causes of DALY for the World in 1999

Rank	Cause	DALYs*	% of total DALYs	Deaths*	% of total deaths
	All conditions	**1 438 154**	**100**	**55 965**	**100**
1	Lower respiratory tract Infections	96682	6.72	3963	7.08
2	HIV	89819	6.25	2673	4.77
3	Conditions during perinatal period	89508	6.22	2356	4.20
4	Diarrheal diseases	72063	5.01	2213	3.95
5	Unipolar major depression	59030	4.10	1	0.00
6	Ischemic heart disease	58.981	4,10	7089	12.66
7	Vaccine-preventable diseases	54638	3.80	1554	2.75
8	Cerebrovascular diseases	49856	3.47	5544	9.90
9	Malaria	44998	3.13	1086	1.94
10	Nutritional deficiencies	44539	3.10	493	0.88
11	Road traffic accidents	39573	2.75	1230	2.19
12	Chronic obstructive pulmonary disease (COPD)	38156	2.65	2660	4.75
13	Congenital abnormalities	36.557	2.54	652	1.16
14	Tuberculosis	33287	2.31	1669	2.98
15	Falls	30950	2.15	347	0.62
16	Maternal conditions	26101	1.81	497	0.88
17	Self-inflicted	25095	1.74	893	1.59
18	Sexually transmitted diseases (excluding HIV)	19747	1.37	178	0.31
19	Alcohol use	18743	1.30	60	0.10
20	Bipolar disorder	16368	1.14	5	0.00

** Values are expressed in thousands.*
Data source: WHO Global Burden of Disease Study, 1999.

Table 3. Burden of Disease Attributable to Selected Risk Factors in the World, 1990

Risk Factor	Deaths*	% of total deaths	DALY*	% of total DALY
Malnutrition	5881	11.7	219575	15.9
Poor water supply, sanitation and personal and domestic hygiene	2668	5.3	93392	6.8
Unsafe sex	1095	2.2	48702	3.5
Tobacco use	3038	6.0	36182	2.6
Alcohol use	774	1.5	47687	3.5
Occupational	1129	2.2	37887	2.7
Hypertension	2918	5.8	19076	1.4
Physical inactivity	1991	3.9	13653	1.0
Illicit drug use	100	0.2	8467	0.6
Air pollution	568	1.1	7254	0.5

** Values are expressed in thousands*
Data source: WHO World study.

Projections of future burden of disease and risk factors are extremely useful for the decision-making process. The secular trend analyses allow for an approximate prediction of the burden of disease at any moment in the future. At Harvard School of Public Health, Murray and Lopez (3) performed a study, which revealed that by 2020, the ranking of burden of disease is expected to be dominated by ischemic heart disease, unipolar major depression and road traffic accidents (see Table 4). By contrast, diseases affecting mostly children at present are projected to decrease due to the globalization of immunization campaigns.

Table 4. Projected Change in Rank Order of DALYs for the 15 Leading Causes in 2020 compared with 1990

Rank by Year:		
2020	**1990**	**Disease or Injury**
1	5	Ischemic heart disease
2	4	Unipolar major depression
3	9	Road traffic accidents
4	6	Cerebrovascular disease
5	12	COPD
6	1	Lower respiratory tract infections
7	7	Tuberculosis
8	16	War
9	2	Diarrheal disease
10	28	HIV
11	3	Perinatal conditions
12	19	Violence
13	10	Congenital abnormalities
14	17	Self-inflicted injuries
15	33	Trachea, bronchus and lung cancers
Reprinted from Murray and Lopez Study		

In Romania, the Institute of Public Health Bucharest has also performed a study aiming to assess the burden of disease for 1998. The study revealed that the predominant causes of DALYs in Romania are the non-communicable diseases and accidents, a pattern similar with the American one rather than the world pattern. Ranking order of DALYs in Romania is presented in Table 5.

Table 5 shows that the burden of mental and behavioral disorders is placed on the third rank, like in the predicted American pattern for 2020. The same study revealed that there are 7 deprived districts in Romania, clustering in the south and western part of the country.

Table 5. Ranking order of DALY in Romania, 1998

Group of diseases	DALYs (years)	% of total DALY
1. Cardiovascular diseases	1 350 203	31,88
2. Cancers	426 951	10,10
3. Mental and behavioral disorders	422 853	9,98
4. Accidents, injuries, poisonings	376 500	8,89
5. Central nervous system diseases	307 684	7,26
6. Digestive system diseases	267 621	6,32
7. Respiratory system diseases	242 524	5,72
8. Infectious diseases	82 802	1,95
9. Congenital abnormalities	69 715	1,64
10. Perinatal conditions	52 317	1,23
11. Genitourinary system diseases	46 550	1,09
12. Endocrin and nutrition diseases	44 032	1,04
13. Blood diseases	39 615	0,93
14. Diabetes	24 916	0,58
15. Bones diseases	14 877	0,35
16. Pregnancy, delivery conditions	13 174	0,31
17. Organic mental disorders	10 183	0,24
18. Tuberculosis	2 049	0,04
19. Skin diseases	1 358	0,03
20. Other	438 963	10,41
Total	4 232 887	100
Data source: Study performed by IPHB.		

EXERCISE: Disability-Adjusted Life Years as a Key Tool for the Analysis of the Burden of Disease

Task: Students read the two files containing WHO reported data on Mortality and DALY (www.who.int/whosis/menu.cfm). After that, they should:

– compare the mortality rankings with DALY rankings and comment the differences; and

– compare DALY rankings between different WHO areas and comment the differences.

References

1. Michaud C, Murray CJL, Bloom B. Burden of Disease – Implications for Future Research, JAMA, vol. 285(5), February 7, 2001.
2. World Health Organization. The World Health Report 2000: Health Systems: Improving Performance, Geneva: World Health Organization, 2000.
3. Murray CJL, Lopez AD. The Global Burden of Disease: A Comprehensive Assessment of Mortality and Disability from Diseases, Injuries and Risk Factors in 1990 Projected to 2020, Cambridge, Harvard School of Public Health, 1996.

Recommended Readings

- www.who.int/whosis/menu.cfm click on Burden of Disease project, then on GBD 2000 Documentation. You can find there: Guidelines (GBD 2000 Guidelines for Epidemiological Reviews), Paper 36 (This discussion paper provides an overview of the Global Burden of Disease 2000 project: its aims, methods and data sources, and Version 1.0 results as reported in the World Health Report 2001), Paper 50 (This discussion paper provides an overview of the Global Burden of Disease 2000 project: its aims, methods and data sources, and Version 2.0 results consistent with the estimates for 2001 reported in the World Health Report 2002), Summary Measures of Population Health (Recent WHO publication addressing a wide array of critical issues regarding the measurement of population health using comprehensive indices combining information on mortality and ill-health).

In BMJ collection (http://bmj.com): search/archive keywords: Disability Adjusted Life Years:

- Trude Arnesen, Erik Nord. The value of DALY life: problems with ethics and validity of disability adjusted life years, BMJ November 1999
- John Wright, John Walley. Health needs assessment: Assessing health needs in developing countries, BMJ June 1998
- Luc Bonneux, Jan J Barendregt, Wilma J Nusselder, Paul J Van der Maas. Preventing fatal diseases increases healthcare costs: cause elimination life table approach, BMJ January 1998
- Kamran Abbasi. The World Bank and world health: Under fire, BMJ April 1999

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Calculating the Potential Years of Life Lost**
Module: 1.7	**ECTS (suggested): 0.25**
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Keywords	Premature death, potential years of life lost, mortality pattern, trend analysis, priority setting
Learning objectives	At the end of this course, students should: • identify the basic concepts of potential years of life lost assessment; • be able to des cribe the factors influencing the calculation of PYLL; and • be able to describe and compare the health status of population based on potential years of life lost methodology.
Abstract	This course covers the following topics: The concept of premature death - historical background; Computing methods for PYLL; Other Approaches for calculating PYLL; Main domains where PYLL is a useful tool; Examples from Romania; and Exercise.
Teaching methods	This course covers the following topics: The concept of premature death - historical background; Computing methods for PYLL; Other Approaches for calculating PYLL; Main domains where PYLL is a useful tool; Examples from Romania and Exercise.
Specific recommendations for teacher	It is recommended that the module will be organized within 0.25 ECTS credits, out of which 3 hours will be done under supervision (lecture and exercise solving), and the rest is individual student's work. Examples of studies performed in their own countries should be used.
Assessment of students	1. Reports presented by each group can be considered as assessment. 2. An essay on the types of interventions required in their own countries based on information existing on WHO site, or studies performed at national / local level.

CALCULATING THE POTENTIAL YEARS OF LIFE LOST

Aurelia Marcu

Potential Years of Life Lost (PYLL) represent a part of potential demography, based on the primary concept "potential of life". This concept is defined as the number of years a person / a group / a population is expected to live between certain ages or until end of life. These years can be lost due to premature death.

The concept of premature death - historical background

The concept was used for the first time by Petti during the XVII century. It was further used in '70s by Canadian and French researchers. In 1977, Romeder and McWhinner proposed a new indicator "potential years of life lost between 1 and 70 years of age" for the purpose of ranking the causes of death (1). Since then, this indicator was used for health planning as a "social indicator".

Computing methods for PYLL

I. The classical approach:

The most used formula to compute PYLL is:

$$\text{PYLL} = \sum_{i=1}^{13} d_i(65 - a_i) \quad = \quad \sum d_i W_i$$

where:

i = number of 5-years age groups (see the table below)

d_i = number of deaths within each age group

65 = upper limit for which a death is considered premature

a_i = age group middle point

Class No.	Age Group	a_i	$W_i = 65 - a_i$	d_i	$d_i W_i$
0	1	2	3	4	5=3 x 4
1	< 1	0,5	64,5=65-0,5		
2	1 - 4	3	62		
3	5 - 9	7,5	57,5		
4	10 - 14	12,5	52,5		
5	15 - 19	17,5	47,5		
6	20 - 24	22,5	42,5		
7	25 - 29	27,5	37,5		
8	30 - 34	32,5	32,5		
9	35 - 39	37,5	27,5		
10	40 - 44	42,5	22,5		
11	45 - 49	47,5	17,5		
12	50 - 54	52,5	12,5		
13	55 - 59	57,5	7,5		
14	60 - 64	62,5	2,5		
					$\Sigma =$

Due to the fact that age represents a continuous quantitative measure, one can use the following formula to calculate a_i:

$$a_i = \frac{\text{lower limit of class "i"} + \text{upper limit of class "i+1"}}{2}$$

Some comments are necessary concerning the interval limits used to compute PYLL:

a) *Lower Age Limit:* Some authors do not take into account the first year of life because the maximum risk of death is encountered close to the delivery time; also during this period of time most causes of death are different from other age groups resp. of endogenous nature; economic investment is modest during this period etc. Other researchers set the lower limit to "0" years, justified by the deficiencies of the reporting systems (in most current health information systems there are data related to infant deaths (0-1) at national level - as total number of deaths but not for all causes of death.

b) *The upper age limit* (65 years) is established according to the existing level of crude mortality rate and of life expectancy at birth.

For countries having a low economic level of development, with a low level of life expectancy at birth, the upper age limit must be decreased, in any case below the level of life expectancy at birth. Conversely, for the developed countries, where the life expectancy at birth is higher than 70 years, the upper age limit should be established at 70 or even 75 years.

For the potential years of life lost due to a certain disease or groups of diseases, age limits are established according to the natural history of this disease and to the research objectives. Examples are AIDS, liver cirrhosis, and suicide:

- In Spain, the age limits for AIDS were established at 25-44 years (2) or 20-39 (3); the key argument for choosing these limits was the natural history of disease: in Spain, the main ways of transmission were sexual intercourse and intravenous drug abuse. In Canada, Hogg (4) recommended in 1996 the use of 1-75 years interval for AIDS.
- For liver cirrhosis, Lessa (5) recommended in 1996 to establish the age interval at 20-59 years for calculating PYLL; he considered that before the age of 20, it is almost impossible that somebody dies from liver cirrhosis.
- For suicide, a cause of death with an increasing frequency, mainly among men and in youth in Romania, Darragh (6) or Riley (7) used the potential years of life lost before 45 years of age.

As a general remark, no matter of country or researcher, for chronic diseases with a long duration, the classical age limits for calculating PYLL are 1-65 or 75 years.

II. Other approaches for calculating PYLL:

During the last 3-4 decades, more refined approaches to calculate PYLL were proposed.

1) *Calculation of the absolute number of years lost by death before the age of 65 - 70 - 75 years:* This number can be computed for the national level, for a geographical area (district, city), for urban / rural area, for men / women, or by group of diseases or even group of diagnoses (if the frequency of a diseases is high, especially among youth). Two, at maximum three characteristics can be commonly combined to compute PYLL.

2) *Calculation of the structure of PYLL according to certain characteristics*: The proportion of PYLL can offer valuable information about the relative importance of each characteristic in generating premature death. It also

offers the possibility of problem ranking, thereby facilitating the priority setting process.

When PYLL is calculated for geographical areas (by district, by country), confidence limits can be estimated for the country mean. This method allows the identification of those areas where the number of deaths is significantly higher than the "expected" one. According to the calculated confidence limits, the districts can be split in three categories:

- districts placed inside the confidence limits. For these districts, the level of PYLL is close to the country mean, observed variations being explained only by the intrinsic variability of the phenomenon.
- districts placed below the lower limit of the confidence interval. For these districts, the number of potential years of life lost is significantly lower than the country mean, therefore being in a favorable position.
- districts placed above the upper limit of the confidence interval. These are deprived areas, where a significantly higher number of potential years of life are lost. From a public health view point, these districts represent a priority for intervention.

3) *For the calculation of the geographical disparities of PYLL, also specific techniques to characterize frequency distributions can be used* (8): quartiles, medians, and percentiles. In order to apply these statistical parameters, several common steps must be accomplished:

- ranking the districts (areas) according to a certain characteristic proportion (e.g. proportion of PYLL by an infectious disease like tuberculosis), in ascending order;
- computing the cumulative frequency;
- calculating the median value. Districts placed within the upper half of the ordered series representing high proportions of PYLL can be considered as deprived.

The quartiles basically divide the ordered series into 4 equal sub-series (Q1 - Q4).

Districts are then placed accordingly within any quartile. Districts placed within the first quartile (Q1) are in a favorable situation, while districts placed within the fourth quartile (Q4) are the deprived ones. Districts placed within Q2 and Q3 can be considered as having a middle position.

Percentiles can be calculated starting from the relative cumulative frequency (presented as percent). A threshold percentile has to be established.

4) *The average number of years lost per premature death (before age of 65, 70 or 75)*: It represents a simple mean. A higher value of this mean emphasizes a higher death frequency among young age groups, consequently a higher social impact of premature death. The formula for calculating the average number of years lost with a premature death is:

$$\text{Average number of PYLL / premature death} = \frac{\text{Total number of PYLL}}{\text{Number of premature deaths}}$$

Different characteristics can again be considered for calculating the average number of years lost for a premature death: by district (administrative unit), by residence (urban/rural), by group of diseases, by gender. The results can be used as a guideline for a priority setting process identifying geographical disparities.

5) *Calculation of the number of potential years of life lost per 1000 inhabitants*: This calculation reflects the impact of premature death on the whole population.

$$\frac{\text{Absolute number of PYLL}}{\text{Population at } 1^{st} \text{ July}} x1000$$

This indicator was used to underline the impact of PYLL (calculated for 5 causes of premature death: cardiovascular diseases, neoplasm, digestive system diseases, accidents and respiratory system diseases) at whole population level.

6) *The standardized PYLL ratio*: It is well-known that the risk of death is strongly influenced by age. This is why Dever (9) proposed the use of standardized PYLL ratio. It is recommended to use this indicator only for comparisons, as it does not describe the real magnitude.

An expected number of PYLL is calculated under the hypothesis that the frequency of premature death in all areas is the same within each age group (a standard mortality pattern is used). The observed value (calculated from real data) is divided by the expected value. If the ratio is higher than 1, it means that the frequency of premature death is higher than expected. This result can emphasize a health problem in the area. It is obvious that the favorable situation is represented by a ratio smaller than 1, suggesting that the premature deaths do not represent a problem in the area.

The formula for calculating the direct standardized PYLL ratio is:

$$PYLL = n\sum_{i=1}^{13} \frac{n_{i0}}{n_0} x \frac{d_i}{n_i} w_i$$

where:

n = total number of population under study

n_i = number of population within "i" age group

n_0 = total number of standard population

n_{i0} = number of standard population within "i" age group

$n_0 = \sum n_{i0}$

$n = \sum n_i$

d_i = number of deaths within "i" age group of population

$w_i = 65 - a_i$

7) *PYLL related to the life expectancy:* The following formula was used:

$$PYLL = \sum d_i e_i$$

where:

d_i = observed deaths within "i" age group

e_i = life expectancy for "i" age group

Main domains where PYLL is a useful tool

1) *The analysis of mortality patterns - impact evaluation of certain causes of death*

The concept of premature death is more and more used for the analysis of mortality patterns due to the increase of life expectancy at birth, the slightly increasing trend of the crude mortality rate, the change of morbidity patterns (decreasing frequency of communicable diseases together with an increasing trend of chronic disease prevalence).

The relative importance of the different causes of death is clearly distinct depending on the method used: PYLL reflect those causes of death affecting mainly the young population, the active one, consequently causing the biggest economic loss. The economic loss includes the visible loss (the person ends to produce) and the hidden loss (the society doesn't recover the educational investments for the young lost person).

For example, in developed countries the hierarchy of the main causes of death is: cardiovascular diseases, tumors and accidents. The same hierarchy according to PYLL is: accidents, tumors and cardiovascular diseases.

Some examples of PYLL analysis: in Spain 52,3% out of all premature deaths are due to accidents (10), in Denmark 34% (11).

2) *Descriptive epidemiology of diseases (groups of diseases) - trend analysis*

In the framework of descriptive epidemiology, the concept of PYLL is used to describe the different diseases according to some characteristics (gender, age group, residence, and district). PYLL was used most frequently to describe:

- accidents
- suicide
- cancer

Repeated cross-sectional studies allow identifying the changes in the hierarchy causes of premature death due to interventive actions.

3) *To identify and rank health problem*

PYLL are often used to identify and rank the health problems at different levels: national, district, city. The decision-makers can plan the interventive actions based on PYLL hierarchy.

4) *Useful for the design of health programs*

PYLL are useful for:

- Identifying the persons to be included in the health programs (target population),
- Establishing the health programs objectives,
- Evaluating the intervention / health programs results / outcomes,
- Cost-Effectiveness Analysis.

In 1990, in Japan (12) have used PYLL to evaluate the efficacy of a screening program for uterine cancer. The efficacy criterion was the degree (%) of PYLL reduction. The reduction percent was directly correlated with the screening coverage degree for the female target group.

In Canada (13), 2 risk factors have been addressed: smoking and alcohol consumption, both of them responsible for several non-communicable diseases. Consequently, 10% of PYLL in Canada were attributable to smoking, associated with alcohol consumption.

Wigle estimated (14), also in Canada, that 50% of premature deaths can be prevented by control of smoking, hypertension, hypercholesterolemia, diabetes and alcohol abuse. Only 12% of premature deaths can be prevented by improving the health care services.

Examples from Romania

The Institute of Public Health in Bucharest has performed several studies to evaluate the health status of the Romanian population, using different methods, in order to support the Ministry of Health in developing adequate health policies and programs.

One of these studies was based on the evaluation of the impact of premature death (before the age of 65) by calculating the Potential Years of Life Lost for the period 1994 - 2000.

According to this study, during this period of time, the ranking of PYLL due to the top 5 causes was relatively stable among men:

1. accidents, injuries and poisonings (25% of total PYLL)
2. cardiovascular diseases (20-21%)
3. cancers (12-14%)
4. respiratory diseases (12-10%)
5. digestive diseases (8-9%)

Among men, the weight of premature death due to cancers has increased, while the weight of premature death due to respiratory diseases has decreased during this period. Considering the same ranking among women, it can be noticed that the pattern is variable year by year. Nevertheless, the most important cause of premature death among women for the whole period was cancer, with an increasing trend from 17% in 1994 to 22% in 2000. Table 1 is summarizing the results for the year 2000.

Table 1. Structure of PYLL by top 5 causes, Romania, 2000

Rank	Total	%	Rank	Men	%	Rank	Women	%
1	***Accidents***	21.1	1	***Accidents***	24.8	1	***Cancers***	21.9
2	Cardiovascular disease	20.4	2	Cardiovascular disease	21.5	2	Cardiovascular disease	18.2
3	Cancers	17.1	3	Cancers	14.6	3	Accidents	13.9
4	Respiratory diseases	11.3	4	Respiratory diseases	10.4	4	Respiratory diseases	13.2
5	Digestive diseases	8.7	5	Digestive diseases	8.6	5	Perinatal conditions	7.7

Source: IPHB study, 2002

It can also be noticed that the ratio PYLL / 1000 men to PYLL / 1000 women was almost stable. According to these findings, two health priorities have been identified for the decision-makers: accidents among men and cancers among women.

EXERCISE: How to Calculate Potential Years of Life Lost (proposed by Adriana Galan)

Task: Students should read the two files containing WHO reported data on Mortality and YLL (years of life lost due to premature deaths) 2001, available at URL: http://www3.who.int/whosis/menu.cfm?path=whosis,burden,burden_estimates&language=english. After that, they should:

- compare the mortality rankings with YLL rankings and comment the differences; and
- compare YLL rankings between WHO areas and comment the differences.

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14. Wigle DT. Premature deaths in Canada: impact, trend and opportunities for prevention. Can J Public Hlth 1990; 5: 376-81.

Recommended Readings

In BMJ collection (http://bmj.com): search/archive keywords: Potential Years of Life Lost

- David Blane, Frances Drever. Inequality among men in standardised years of potential life lost, BMJ July 1998
- Janice Hopkins Tanne. Cause of death among Americans differs with race and education, BMJ November 2002
- Martin McKee, Vladimir Shkolnikov. Understanding the toll of premature death among men in eastern Europe, BMJ November 2001
- Zosia Kmietowicz. Government policies set to narrow „health gap", BMJ September 2000

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Case Study: Inequalities in Health as Assessed by the Burden of Disease Method**
Module: 1.8	**ECTS (suggested): 0.25**
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Keywords	Health inequalities, burden of disease, health vulnerability, non-fatal health outcomes
Learning objectives	At the end of this exercise, students should: • be aware of the complexity of health inequalities assessment; • be able to describe the weaknesses of present studies aiming to assess the health inequalities; • be able to describe the advantages of using Disability Adjusted Life Years (DALY) as a composite indicator in studies of health inequalities.
Abstract	This course gives a short literature review on studies about health inequalities, along with their weaknesses (shortcomings of research, descriptive rather than analytical, methodological and conceptual problems, and study design problems). Here are also short presentation of DALY concept and the advantages of using this composite indicator in studies aiming to assess the health inequalities.
Teaching methods	Interactive group discussion of each paragraph, revealing the key concepts and main conclusions. Each concept or general remark will be written on a flipchart.
Specific recommendations for teacher	This module to be organized within 0.25 ECTS credits, out of which Case Study takes 2 hours of discussions and will follow the module of Disability-Adjusted Life Years as a Key Tool for the Analysis of the Burden of Disease. Another 4 hours will be destined to individually review electronic and printed literature in the field.
Assessment of students	A short (max. one page) essay developing the three main ideas selected during the exercise will be assessed.

CASE STUDY: INEQUALITIES IN HEALTH AS ASSESSED BY THE BURDEN OF DISEASE METHOD

Khaled Yassin, Adriana Galan

Today there is a general consensus that health inequalities still persist and in some cases have even been increasing not only in developing countries, but in Europe as well. Since the late 1970s, an increasing number of studies have provided ample evidence of the growing gap in health between different social groups. For example, it was consistently proven that people at a socio-economic disadvantage suffer a heavier burden of illness and have higher mortality rates than their well-off counterparts (1,2,3,4,5,6,7,8). These observations have refuted previous arguments that health inequalities were disappearing, or had disappeared in European societies.

These socio-economic inequalities in health are a major challenge for health systems, not only because most of these inequalities can be considered unfair, but also because a reduction in the burden of health problems in disadvantaged groups offers a great potential for improving the average health status of the population as a whole. Furthermore, understanding health inequalities in a given community can improve the effectiveness and efficiency of the health care delivery by ensuring that appropriate interventions are delivered to the population at risk.

Recognizing the need to devote research attention to the question of health inequalities in modern industrial societies, we carried out a *situation analysis* in order to identify needs and, on this basis, prioritize areas for research. This review revealed the following points:

Firstly, while some progress has been made in studying health inequalities, this progress is not evenly witnessed in all European countries. The question has been explored more in countries such as the United Kingdom, Finland and Sweden than, say, in Germany, Italy and Spain.

Secondly, research studies of health inequalities focus traditionally on proving the existence of inequalities among broad social groups, rather than investigating or illuminating the reasons for such inequalities and the dynamics of their occurrence. Equally neglected is the description of the most vulnerable groups. As a result, outcomes of many of these studies have been too general to form the basis for concrete action.

Thirdly, the concepts of health vulnerability and strategies for coping with socio-economic disadvantage have been seldom considered in research of health inequalities in Europe or elsewhere. Inequalities have been examined among different social groups using various indicators for poverty, income, occupation, education, etc. Whereas poverty is basically an absolute and economically determined concept, vulnerability is a relational and social one. It does not conceive inequalities as numbers of people with certain occupations, level of education, or of a certain gender having heavier burden of mortality or morbidity from certain diseases. Rather, vulnerability research attempts to understand inequalities as real people coping with uncertainty and risk within real societies.

Health vulnerability is not defined in terms of percentage of income relative to national standards, but a question of defenselessness, insecurity and exposure to risk, shocks and stress. The point is that although poverty may be a proxy indicator, it does not necessarily amount to the vulnerability. The feasibility of action plans based on vulnerability findings differs from one based on results of poverty research. Vulnerability has three dimensions: (1) the risk of exposure to health threats; (2) the risk of inadequate capacities to cope with the imposed health threats; and (3) the risk of severe consequences. Consequently, the most vulnerable groups are those most exposed to health threats and those possess the most limited coping capabilities and suffer from the most severe consequences and are endowed with the most limited capacity for recovery.

Fourthly, there are several design problems that adversely affect the validity and comparability of studies of health inequalities. Such studies were to attain the twin goals of measuring health and measuring inequalities. Several indicators are traditionally used to measure health such as perinatal and infant mortality, all-cause and major-cause mortality, reported chronic illness, subjective sense of wellbeing, and the incidence of certain diseases. Mortality indicators, although helpful, do not include the level of suffering and disability from non-fatal outcomes of diseases. Subjective ratings of health are shown to be confounded by the differing thresholds among different social class groups for recognizing or reporting ill-health or disability. Disease-specific measures are very selective because while the morbidity from some diseases is more prevalent in disadvantaged social groups, some others are more prevalent in the more advantaged ones.

Measuring inequalities is not less troublesome than measuring health as about dozen different methods are being currently used. They vary in accuracy, complexity and ‘informativity’. It is quite obvious that there are huge di-

fferences between the measures used in the study of health inequalities (9,10,11,12,13,14,15,16,17). These differences in addition to differences in the quality of data collected over different periods of time or among countries are good justifications for interpreting them cautiously.

Studies of health inequalities have focused on comparing mortality indices among different social groups. Such approach assumes death alone can reflect the burden of disease and differentials in mortality indicators can therefore mirror the health inequalities between these groups. Death, however, is not the only consequence of disease. A wide array of scenarios can follow a morbid condition. This can include full recovery, a period of disability followed by full recovery, a period of disability followed by death or permanent disability. These non-fatal outcomes constitute a significant part of the burden of disease, which has been ignored by the previously mentioned indicators.

The few studies that considered the burden of non-fatal health outcomes were tailored to specific diseases (diabetes, rheumatoid arthritis, etc.) in particular groups. Furthermore, the fact that nearly all these measures are based on self-reports explains why the reliability and validity of such measures have been long questioned especially when inter-community and inter-temporal comparisons are attempted.

Given these shortcomings in current measures of the burden of fatal and non-fatal consequences of disease, the World Health Organization and the World Bank endeavored the Disability Adjusted Life Years (DALYs) as a measurement unit of the burden of disease (18). The DALY has been successfully used to assess the global burden of disease and the WHO has advocated the use of DALY to study health inequalities as well. The DALY is a composite indicator of the burden of disease, which incorporates both the years of life lost due to premature mortality and varying degrees of disability. The DALY expresses therefore years of life lost due to premature death and years lived with a disability of specified severity and duration secondary to these priority diseases. One DALY is thus one lost year of healthy life. A premature death is defined as one that occurs before the age to which the dying person could have been expected to survive according to the life expectancy in the European society.

Using the DALY in studies of health inequalities envisages several advantages. First, the DALY is the only measure that can infuse information about non-fatal health outcomes into debated of health inequalities. Second, the DALY uncouples social and epidemiological assessment of health inequalities from advocacy. Third, the DALY can measure the magnitude of premature

death and non-fatal health outcomes attributable to proximal biological causes, including diseases and injuries or attributable to more distal causes such as poor living standards, tobacco use or socio-economic determinants. Fourth, the DALY is a stable measure that can be used for purposes of comparisons either between different communities or between different points of time.

EXERCISE: Inequalities in Health in the European Region: What Can the Burden of Disease Methodology Offer?

Task: Based on the list of key concepts and conclusions revealed under supervision during the group discussion, students will be asked to make a summary of these ideas and select the most 3 important and useful of them on their opinion. Give some reasons for this selection.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT **A Handbook for Teachers, Researchers and Health Professionals**	
Title	**Health Technology Assessment as a Tool for Health Systems Development**
Module: 1.9	**ECTS (suggested): 0.50**
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Keywords	Health technology assessment, decision-making in health purchasing, policy and practice, quality of care, outcomes research, decentralization/centralization, evidence-based knowledge
Learning objectives	For many years this topic covered financial analysis and acquisition planning for high technology in health care. The basic premise of this course is that the purpose of assessment of a particular technology (including elements of technology itself, patient/citizen, organization and economy) is to discover the „true cost" of health produced by application of that technology. After completing this module students and public health professionals from a variety of backgrounds should: Obtain • An overview of a background and origins of health technology assessment • An introduction to the scientific methods and instruments in health technology assessment Summarize • The four main elements of a health technology assessment analysis - the technology, the patient/citizen, the organization and the economy. • The steps that have to led to the assessed health technology Examine • How decision-maker's questions are specified in health technology assessment • How literature is searched and collected • How studies could be designed • How data can be collected and analyzed • How published health technology assessments could be validated
Abstract	Health technology assessment methods are evolving and its application are increasingly diverse. This module introduces certain fundamental aspects and issues of a dynamic field of inquiry. Broader par-

	ticipation of people with multiple disciplines and different roles is enriching the field. Like the information required conducting most assessments, the body of knowledge about health technology assessment cannot be found in one place and is not static. Practitioners and users of health technology assessment should not only monitor changes in the field, but they should contribute to its development. CONTENT Background Origins What is health technology? What is health technology assessment? What is the purpose of health technology assessment? Is it health technology assessment or a different approach that is needed? What are the main elements of HTA analysis? When are health technologies assessments requested? What is the role of ethics in health technology assessment? How is health technology assessment conducted? Selected issues in health technology assessment Case example References
Teaching methods	Teaching methods include: Lectures; Study of literature in small groups (up to five students); Guided discussion on previously done exercises and case problems; Preparing a project report (in a group of three students) on one topic for a certain health technology.
Specific recommendations for teacher	The topic allows a good combination of theoretical knowledge with practical skills. Knowledge in quantitative and qualitative research designs and measurement issues; various methods from statistical, over informatics to economic is already expected from the student, as well as skills in computer and language.This module should be only first in line with three lectures, 6 exercises and group/individual work (three times).
Assessment of Students	Project work with defense of the study; and Multiple choice questionnaire.

HEALTH TECHNOLOGY ASSESSMENT AS A TOOL FOR HEALTH SYSTEMS DEVELOPMENT

Jelena Marinković

Worldwide, publicly funded health services are under pressure due to demographic changes, growing expectations, and the development of new technologies. Of these three major pressures, new technologies are generating the most concern and the most dramatic response (1,2,3). Still, new technologies can benefit health and disability service consumers in many ways. Some directly improve quality of life or life expectancy. Others act more indirectly, for example, by increasing the efficiency of the health system. However, new technologies are often introduced before there is adequate information about safety, effectiveness and ethical and social acceptability.

Origins

Technology assessment (TA) arose in the mid-1960s from an appreciation of the critical role of technology in modern society and its potential for unintended, and sometimes harmful, consequences. Experience with the side effects of a multitude of chemical, industrial and agricultural processes, and such services as transportation, health and resource management contributed to this understanding (4). TA was conceived as a way to identify the desirable first-order, intended effects of technologies as well as the higher-order, unintended social, economic and environmental effects (5).

Health Technologies (HT) had been studied for safety, effectiveness, cost, and other concerns long before the advent of Health Technology Assessment (HTA). Development of TA as a systematic inquiry in the 1960s and 1970s coincided with the introduction of health care technologies that prompted widespread public interest in matters that transcended their immediate health effects. Health care technologies were among the topics of early TAs. Multiphasic health screening, in vitro fertilization, predetermination of the sex of children, retardation of aging and modifying human behavior by neurosurgical, electrical or pharmaceutical means were among the first, „experimental" assessments.

Since its early years, HTA has been fueled in part by emergence and diffusion of technologies that have evoked social, ethical, legal, and political concerns. Among these technologies are contraceptives, organ transplantation, artificial organs, life-sustaining technologies for critically or terminally ill patients, and, more recently, genetic testing and genetic therapy. These technologies have challenged certain societal institutions, codes, and other norms regarding fundamental aspects of human life such as parenthood, heredity, birth, bodily sovereignty, freedom and control of human behavior, and death (6).

HTA is the only field of TA so far which has gained a distinctive profile in the sense of a particular subject, client, expertise and specialized institutions. HTA like TA in general aims at supporting decision making by providing comprehensive information on the preconditions for, and consequences of the implementation of new technologies (7).

What is health technology?

Goodman defines technology as the application of scientific or other organized knowledge - including any tool, technique, product, process, method, organization or system - to practical tasks. In health care, technology includes drugs; diagnostics, indicators and reagents; devices, equipment and supplies; medical and surgical procedures; support systems; and organizational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation (4).

According to the World Health Organization's (WHO) „Health for all Policy in the 21st century", released in January 1998, the scope of technologies for health, extends from those technologies that provide a direct benefit to health (such as molecular genetics, biological, pharmaceuticals, and medical devices), to those that support health system functions (like telecommunications, information technologies, devices for environmental protection and food technologies).

The International Network of Agencies for Health Technology Assessment (INAHTA) defines health technology as prevention and rehabilitation, vaccines, pharmaceuticals, and devices, medical and surgical procedures, and the systems within which health is protected and maintained (8).

Under broad definitions such as these, the phrase „health (healthcare, medical) technology" can be used in both diagnostic and therapeutic settings and under either individual or population health approaches. Health technologies might include, for example, chemotherapy for cancer, hearing aid techno-

logy, electronic fetal monitoring, population screening for breast cancer, coronary artery bypass surgery, and magnetic resonance imaging.

As the field of health technology assessment has evolved, these definitions have come to be seen as a fairly narrow definition of technology. In part, this has been due to a growing recognition that the arrangements and structures for delivery of drugs, device and procedures can have far reaching impacts not only on the use of technology but also outcomes of patients. To reflect the importance of these and other factors a more comprehensive definition of health technology is given by Kristensen. He defines very broadly that health technology is the practical application of knowledge in relation to health and disease (9).

With the health problem as the starting point, according to Bakketeig (10), the aim of the technology can roughly be divided into following: preventive care (aimed at preventing diseases from occurring), screening (aimed at detecting early signs of diseases or risk factor, with the aim to slow down the development of the disease), diagnosis (aimed at identifying the diseases in patients with clinical signs and symptoms), treatment (seeking to maintain health status, cure the patient or provide palliation), rehabilitation (which takes its starting point in the treated, but still ill patient and seeks to restore the functioning or minimize the consequences of dysfunction or defects).

What is health technology assessment?

While there is no widespread consensus on the definition of health technology assessment, for a long time a widely accepted definition was that of the United States Office of Technology Assessment (OTA) that it is the field of research that evaluates the short and long-term consequences of individual medical technologies on individuals and society (11).

HTA is related to research due to its methods, but is also related to planning, administration, and management due to its focus on decision-making. Thus, HTA can be seen as a bridge between science paradigm and a policy paradigm (12).

In Europe in mid nineties HTA is seen as a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision (13). HTA beside the benefits and financial costs of a particular technology or group of technologies also includes studies of ethical and social consequences of technology; factors speeding or impeding development and diffusion of health technology; the effects of public policies on diffusion and use of health tech-

nology and suggested changes in those policies; and studies on variation in use of technologies (13).

Goodman defines HTA as a systematic evaluation of properties, effects, and/or impacts of health technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods (4).

The International Network on Agencies for Health Technology Assessment defines HTA as multidisciplinary field of policy analysis that studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology (8).

The broadest one is given by Kristensen who defines health technology assessment as a research based, applied assessment of relevant available knowledge of problems, when applying technology in relation to health and disease. HTA is a comprehensive, systematic assessment of the conditions for, and the consequences of using health technology (9).

What is the purpose of health technology assessment?

The purpose of HTA is to assist health policy makers, managers and health professionals at local and national levels in making informed decisions both in health purchasing, policy and practice. HTA information may be particularly useful in supporting decisions when: an established technology is associated with significant variations in utilization or outcomes, a technology is highly complex or involves significant uncertainty, a technology has high unit or aggregate cost, explicit trade-off decisions must be made in allocating resources among technologies, or a proposed provision is innovative or controversial.

The essential properties of HTA are the orientation to decision-making and its multidisciplinary and comprehensive nature. The goal of HTA is change. That is, it encompasses all methods used by health professionals to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

Is it health technology assessment or a different approach that is needed?

It is useful to clarify whether HTA is the right instrument to use for the particular problem because it may conceivably be more beneficial to apply a different approach. According to Kristensen et al (9), the set of alternative procedures to clarify the problem are:

Alternative procedures to clarify the problem
1. Health technology assessment
2. A quality-assurance project (if one knows what should be done in particular organizational situation, but what is presently done, is not the right approach).
3. A basis for decision-making developed in the usual administrative framework (if, for instance, a national HTA or an HTA from region is available).
4. A traditional expert and/or stakeholder committee (if the aspect of stakeholders is very important, or if the opinion of particular expertise desired, or if only little time is available).
5. Exclusively a systematic literature review, possibly a meta analysis, to determine the clinical effects and efficiency of the technology.
6. An economic analysis (if sufficient knowledge of the effect and efficiency of the technology is available, and if there are no specific organizational questions).
7. A (primary-) research project (if documented research is simply not available, especially of the clinical effects).

Source: Kristensen FB, Horder M, Poulsen PB (eds.). Health Technology Assessment Handbook. Danish Institute for Health Technology Assessment, 2001.

What are the main elements of HTA analysis?

HTA includes analysis and assessment of a number of areas, where use of the health technology may have consequences. These can be divided into four main elements: the technology, the patient/citizen, the organization and the economy.

Technology. Assessment of technology includes the following main aspects that need to be assessed: field of application, effectiveness and risk assessment. This aspect is covered in more details later on.

Patient / Citizen. Examining the patient / citizen element in HTA is covered with very different methods, as regards theoretical basis and application; from field research that includes participant observation, interviews that include focus group, questionnaire surveys to prospective methods. Frequently measurement process is based on health status and health-related quality of life concept (4,14,15).

Organization. The aim of organizational analysis is to pinpoint some of the dimensions, which can be of importance for how interaction between technology, organization and administration develops, i.e. to describe some of the elements, which could play a part in the interaction between the behavioral patterns around technology, and point out possible consequences of different directions (16,17).

Economy. Economy aspect includes economic, budget or business analysis. The first one is far more important and is mainly conducted at societal level, where economic consequences for society, which means everyone who is directly or indirectly affected by technology, are assessed and included. Budget analysis is applied when investigating who carries the burden in terms of expenditures and who will benefit from the use of technology. At last, business analysis is conducted when the information about needs for investment and the running costs with respect to a technology are important (18).

When are health technology assessment requested?

Assessments can be requested and conducted at any stage in a technology's life cycle.

Stages include: *conceptual* (in the earliest stages of development), *experimental* or *investigational* (undergoing initial testing and evaluation), *pre-established* (adoption of an innovation by certain individuals and institutions); *established* (considered to be a standard approach and diffused into general use); and *outmoded* (superseded by another technology or demonstrated to be ineffective or harmful).

Since technology is constantly evolving, HTA must be viewed as an iterative process. It may be necessary to reassess a technology when competing technologies are developed, the technology itself evolves or new information is introduced.

What is the role of ethics in health technology assessment?

Since HTA is used to make judgments about what ought to be done with health technologies, there is significant overlap between it and medical ethics. According to Goodman (19), conducting a technology assessment requires careful attention to ethical questions, such as:

- Should all assessments be driven by cost concerns?
- Are the individuals involved in the selection of topics, the conduct of the assessment, and the use of its results free of conflicts of interest?
- Are judgments of value implicit in the statement of the assessment problem or the choice of methodology?
- Are informed consent, patient confidentiality and related means for protecting patient welfare in clinical investigations properly implemented?
- Do assessments provide means (e.g., in data collection, synthesis and reporting) to determine how technologies challenge prevailing legal standards and societal norms?
- Are the assessment's recommendations ethically justified?

How is health technology assessment conducted?

HTA process involves: the *identification* of technology, health or health care problems and possible assessments to address these; the *prioritization* of possible assessments; *assessment*; *dissemination* of the findings and conclusions of assessments; the *implementation* of findings and conclusions in policy and practice, and *impact assessment* of resulting change.

The ten steps listed below, according to Goodman, provide a basic classical framework for conducting a health technology assessment (not all assessments involve each of these steps or conduct them in the same sequence) (19):

Ten Steps of Health Technology Assessment
1. Identify and rank assessment topics
2. Specify assessment problem
3. Determine locus or responsibility of assessment
4. Retrieve available evidence
5. Collect primary data (as appropriate)
6. Interpret evidence
7. Synthesize evidence
8. Formulate findings and recommendations
9. Disseminate findings and recommendations
10. Monitor impact of assessment reports

Source: Goodman C, Snider G, Flynn K. Health Care Technology Assessment in CVA. Boston, Mass: Management Decision and Research Center, Washington, DC: Health Services Research and Development Service, 1996.

When new technology is in question this framework has somewhat different stages:

A Framework for New Technology Assessment
1. Horizon scanning - the identification of emerging technologies before they become available for introduction.
2. Prioritization for assessment - deciding which new or emerging technologies should undergo further assessment.
3. Assessment - a research-based process designed to determine whether a new technology is safe, efficacious, effective and efficient.
4. Appraisal - a judgment on the social and ethical acceptability and appropriateness of a new technology. This includes consideration of community need, equity, and opportunity cost.
5. Adoption and diffusion - the process whereby new technologies are taken up in clinical practice.
6. Evaluation - the ongoing assessment of a new technology following its introduction.

Source: National Health Committee. New Technology Assessment in New Zealand. Discussion document, 2002.

The source of next definitions and descriptions is publication „New Technology Assessment in New Zealand", published in year 2002 (20).

Horizon scanning is the process of identifying new and emerging technologies that have the potential to impact on a health system. It essentially involves formal or informal communication between policy makers and experts (21).

New technology assessment requires significant time, expertise and resources. Consequently, it is impossible to assess all emerging technologies. Therefore, *prioritization* for assessment is an essential and crucial part of the framework. There should be an agreed set of criteria against which emerging technologies are prioritized for assessment.

The *assessment stage* is based on empirical research. It aims to establish the effect (safety, efficacy and effectiveness) and efficiency of a new technology. This phase can be costly and labour intensive as it may involve primary research. Where possible, a systematic review of the scientific evidence is performed (mainly using scientific literature from peer-reviewed journals).

The gold standard test for safety, efficacy and effectiveness is a double-blind randomized controlled trial (RCT). However, for several logistical and ethical reasons, it is not possible to conduct double-blind RCTs for all new technologies. Where double-blind RCTs cannot be carried out, it is necessary to rely on the best alternative source of evidence. The task of selecting the best source of evidence is made easier by using well-accepted, levels of evidence (22).

The efficiency (value for money) of a new technology is predicted by economic evaluation. There are several types of economic analysis that can be used to determine „value for money". These include Cost-Minimization Analysis (CMA), Cost-Effectiveness Analysis (CEA), Cost-Benefit Analysis (CBA) and Cost-Utility Analysis (CUA). These may be referred to collectively as efficiency analysis.

The *appraisal* of a new technology involves taking into consideration community need, equity, appropriateness and acceptability, and opportunity cost. In contrast to the assessment phase, appraisal is more of an art than a science. It requires judgments to be made on social values and is informed by understanding of the health and disability sector and society in general. Inputs from professionals, consumers and the wider community are considered to be particularly important at the appraisal stage.

The *adoption and diffusion* stage is relatively self explanatory. As a new technology appears to be of value, patients begin to request it and clinicians begin to use it. Ideally, a new technology that has been assessed and appraised and found to have a potential benefit will be adopted and diffused into the health and disability sector in a controlled manner; that is, the circumstances in which it is used will be agreed on before the technology has been adopted and diffused. In reality, new technologies tend to be adopted and diffused in a rather dis-organized manner.

New technology assessment should be an iterative process rather than a one-off study. *Evaluation* helps to ensure that this is the case. It involves the monitoring and further studying of a technology once it has been introduced. This might include: preparation of qualitative and quantitative data collection systems to receive data for side effects and complications, appropriateness and acceptability of the community for the new technology and outcome measures conducting scheduled milestone evaluation to determine achievement of target evaluation measures collaboration with clinical evaluation and quality improvement programs (23). Evaluation is important because the disease patterns and other characteristics of the population using the technology will inevitably change, and this may have implications for safety, effectiveness, efficiency and so on. In addition, during the initial stages of a technology's life cycle, the skills of practitioners in using the technology are not likely to be much higher. As skill level increases, the balance of risks and benefits associated with the new technology may change considerably.

Selected issues in health technology assessment

Quality of Care and HTA. Quality of care is a measure or indicator of the degree to which health care is expected to increase the likelihood of desired health outcomes and is consistent with standards of health care. Quality assurance involves a measurement and monitoring function (i.e., quality assessment). HTA and quality assurance are distinct yet interdependent processes that contribute to quality of care. HTA generates findings that add to our knowledge about the relationship between health care interventions and health care outcomes. This knowledge can be used to develop and revise health care standards, e.g., manufacturing standards, clinical laboratory standards, practice guidelines, and other agreed upon criteria, practices and policies regarding the performance of health care. In summary, HTA contributes knowledge used to set standards for health care, and quality assurance is used to determine the extent to which health care providers adhere to these standards (24,25).

Outcomes Research and HTA. Outcomes research concerns any inquiry into the health benefits of using a technology for a particular problem under general or routine conditions (26). In practice, the term outcomes research has been used interchangeably with the term effectiveness research since the late 1980s to refer to a constellation of methods and characteristics that overlap considerably with HTA.

Centralization and decentralization of HTA. Although technology assessment have originated as a centralized function conducted by government

agencies or other national- or regional-level organizations, HTA is also a decentralized activity conducted by a great variety of organizations that make technology-related policy decisions (27). As noted before, a HTA done from a particular perspective may not serve the technology-related policymaking needs of other perspectives.

Evidence-based health technology assessment. Eisenberg considers the next ten lessons for evidence-based technology assessment: innovation and flexibility should guide assessment; technology is more than devices; research and assessments should be linked with coverage; technology assessment is not a one-time exercise; new measures of outcomes should be developed; the community of practice is a laboratory for technology assessment; training and capacity building in technology assessment should be emphasized; better international collaboration will result in global synergy; national resources on technology assessment should be linked and technology assessments should be translated into improved practice (28). The same author writes that „Evidence-based technology assessment is a critical public good that can benefit all who are concerned about appropriate use of health services and products. Technology itself is rarely inherently good or bad, always or never useful. The challenge is to evaluate when it is effective, for whom it will enhance outcomes, and how it should be implemented or interpreted. Health technologies will not reach their potential unless they are translated, used, and continuously evaluated".

Case Example:

The example is related to computer-based delivery of health evidence done as a health technology assessment in report „Computer-Based Delivery of Health Evidence: A Systematic Review of Randomized Controlled Trials and Systematic Reviews of the Effectiveness on the Process of Care and Patient Outcomes" done by Cramer et al from The Alberta Research Centre for Child Health Evidence, University of British Columbia, 2003 (29). The basic framework and the explanation are suggested by Goodman (19).

Step 1. Identify and rank assessment topics

Identifying potential topics. /To a large extent, assessment topics are determined, or at least bounded, by the mission or purpose of an organization./

The perspectives opened up by information and communication technology for health and health care go beyond problems of the clinical setting and relate health to general problems of the so called Information Society. Over the past decade, in an effort to assist health professionals with successful-

ly searching for, translating, and integrating the best clinical evidence at the point-of-care, computer-based evidence delivery systems have been developed. These systems have been designed to assist providers with diagnosis, prescription, managing diseases, and preventing diseases. In addition to assisting health professionals, these systems have been designed to assist health care consumers by guiding them in their health behaviors, treatment options and disease management.

Ranking topics. /Some assessment programs have explicit procedures for setting priorities. Others set priorities in ad hoc or informal ways. The following are examples of criteria - listed in no particular order - that might be used to set assessment priorities: high burden of morbidity or mortality; large number of patients affected; high unit or aggregate cost of a technology or health problem; substantial variations in practice; high potential to improve health outcomes or reduce health risks; availability of sufficient research findings to perform the assessment; scientific, professional or public controversy; need to make regulatory decision; need to make payment decision; available findings not widely disseminated or used by practitioners./

Selected topic fulfill most of the criteria listed above and has almost the greatest importance of all ICT application in the field of health.

Step 2. ***Specify assessment problem.*** /One of the most important aspects of an assessment is to specify clearly the question(s) to be addressed; this will affect all subsequent aspects of the assessment. Assessment problem statements should recognize the relation of the new technology to existing technology./

As with any innovative health care intervention, computer-based evidence delivery system need to be rigorously evaluated before their use become widespread (get acquainted with a Health on the Net Foundation - HON - principles, http://www.hon.ch). The objective of this assessment was to systematically identify and synthesize randomized controlled trials (RCT) and systematic reviews (SR) that evaluate the effectiveness of computer-based health evidence delivery systems on the process of care (e. g., compliance with evidence) and / or patient outcomes (e.g., blood pressure).

Step 3. Determine locus of assessment. /The nature of an assessment problem will affect the determination of the most appropriate organization or group to conduct the assessment. A comprehensive assessment addressing multiple attributes of a technology can be very resource-intensive. It can require considerable training and experience in the methods of evidence-based medicine. Factors that influence a HTA „make or buy" decision include: Is an exist-

ing assessment available? If an existing assessment is available, does it address the specific issues of concern to the organization? How recently was it conducted? Is the methodology used sufficiently credible? If an existing assessment needs to be updated or is not available, do people in the organization have the time and expertise to perform the required data collection and analyses? If a synthesis of existing information is needed, does the organization have database searching capabilities, staff to retrieve full text articles, and staff trained in the conduct of systematic reviews? If new data are needed, does the organization have the requisite resources and expertise? What methodology will be used? If a consensus of clinical experts is the preferred methodology, does that consensus need to incorporate and reflect the opinions of the organization's own clinicians? Will local clinicians accept the results and report recommendations if they do not participate in the assessment?/

Step 4. Retrieve available evidence. /One of the great challenges in HTA is to assemble all of the evidence relevant to a particular technology before conducting a qualitative or quantitative synthesis. Although some sources are devoted exclusively to health care topics, others cover the sciences more broadly. Multiple sources should be searched to increase the likelihood of retrieving all relevant reports. Useful sources for relevant evidence include: computer databases of published literature; computer databases of clinical and administrative data; printed indexes and directories; government reports and monographs; reference lists in available studies, reviews and meta-analyses; special inventories of reports; health newsletters and newspapers; company reports; and colleagues and other investigators. Increasingly, most of the sources are accessible via the Internet./

Evidences are taken from published and unpublished randomized clinical trials and systematic reviews that assess the effectiveness of computer-based evidence delivery systems. In this reviews, a comprehensive search of the literature using following databases: Medline (1990-2002), EMBASE (1990-2002), CINAHL (1990-2002), Cochrane Controlled Trials Register (1990-2002), Web of Science (1990-2002), and the trial registry of the Cochrane Effective Practice and Organization of Care Group (1990-2002) was done. In addition, two reviewers independently hand-searched the Health Information and Libraries Journal (1990-2002), Journal of the Medical Library Association (1990-2002), Medical Reference Services Quarterly (1990-2002), and the Proceedings of the American Medical Informatics Association (1991-2002). In addition, individuals from companies (more than 60) that produce relevant products were contacted for information about relevant studies. Finally, authors of all relevant articles and experts in the field are being con-

tacted for information on recent, ongoing, or unpublished studies. This comprehensive search of literature at last identified 13 570 documents of which 525 were deemed potentially relevant for the selected assessment question.

Step 5. Collect primary data. /Compiling evidence for an assessment may entail collecting new primary data after determining that existing evidence will not adequately address the assessment question(s). Methods for generating new data on the effects of health technology ranges from case reports to meta-analysis. The demand for studies of higher methodological rigor (e.g., meta-analysis or RCTs) is increasing among health care technology regulators, payers, providers and other decision makers./

Step 6. Interpret evidence. /Evidence interpretation involves classifying the studies, grading the evidence and determining which studies will be included in the synthesis. Assessors should use a systematic approach to critically appraise the quality of the available studies. Interpreting evidence requires knowledge of investigative methods and statistics./

Two reviewers independently screened 525 articles for relevance using a predetermined set of inclusion criteria and identified 57 relevant randomized controlled trials (RCT) and 10 relevant systematic reviews. The majority of these studies was rated as having low methodological quality and was therefore open to substantial bias. The majority of the RCTs, as well as systematic reviews, were published between 1995-2001 (33 and 9 respectively), and were conducted in North America (46 and 6).

Step 7. Synthesize and consolidate evidence. /For many topics in technology assessment, a definitive study that indicates one technology is better than another does not exist. Even where definitive studies do exist, findings from a number of studies often must be combined, synthesized or considered in broader social and economic contexts in order to respond to the particular assessment questions. Methods used to combine or synthesize findings from different studies include: systematic reviews, meta-analysis, decision analysis and group judgment or consensus development./

One method for providing an evaluation is to summarize the existing evidence in a systematic review. Systematic reviews use explicit and reproducible methods for identifying and selecting primary or integrated studies and assess the methodological quality of each study with respect to the strength of evidence it contains.

Eighteen of the 57 randomized controlled trials investigated systems designed specifically for patient users, 37 studies investigated systems

designed specifically for health care providers, and two studies investigated systems designed for use by both patients and health care providers. Five studies investigated diagnosis systems, 30 investigated management systems, one investigated a prediction system, four investigated prescription systems, nine investigated prevention systems, six investigated support systems, and two investigated treatment systems. The primary outcomes measured varied considerably from study to study and were categorized into one of three groups: process of care (e.g., compliance with medical guidelines), patient health (e.g., blood pressure), and other (e.g., knowledge).

When the data from these studies were pooled, use of these systems was found to enhance the process of care. However, some studies showed a positive effect of these systems on the process of care whereas other studies did not. The variability among the findings of these studies is likely a result of the various differences between the studies such as the intervention studied, the methodological quality, or the specific outcomes assessed. Overall, the use of computer-based evidence delivery systems was not found to have an impact on patient health outcomes. However, there were very few studies that investigated patient health outcomes and in most cases, the studies were too small to detect an effect. In addition, to have an effect on patient health outcomes, these systems must first have an effect on the process of care. Thus it may be too early to investigate patient health outcomes. The effect of these systems on the process of care needs to be enhanced prior to investigating their effect on patient health outcomes.

Six of the ten systematic reviews included studies with experimental designs other than randomized controlled trials and three of the ten assessed studies with designs other than controlled clinical trials. Two included investigations of non-computerized as well as computerized information systems. Eight reviews investigated the effects of these systems on the process of care and seven found a benefit. The effect of these systems on patient health outcomes was tested in eight systematic reviews and four documented a benefit. These findings are consistent with the findings of the review of randomized controlled trials.

Step 8. Formulate findings and recommendations. /Although the terms „findings" and „recommendations" are sometimes used interchangeably, they have different meanings. Findings are the results or conclusions of an assessment; recommendations are the suggestions, advice, or counsel that follow from the findings. Recommendations can be made in various forms, such as options, practice guidelines or directives./

Firstly, findings compromise that there exists great variability among these computer-based systems and the findings of the studies. Thus, there may not be one generic system that works in all environments. There is a need to identify factors that contribute to successful and unsuccessful systems. And, every system needs to be evaluated in the environment where it is implemented. Secondly, compliance with evidence is low with and without the use of these systems. Therefore, there is the need to identify barriers to the uptake of evidence, and where the barriers are inappropriate, to identify methods to remove them.

Broadly, several implications and recommendations for future areas of research can be suggested from this review. First, there is considerable potential for improving the dissemination and use of medical evidence. Future studies employing a qualitative approach are required to identify the barriers to using medical evidence and, where these barriers are inappropriate, the methods to remove them. In addition, because the results of the included studies varied (i.e., some found a benefit of using a computer-based evidence delivery system others did not) further research needs to focus on identifying the specific aspects of a system that contribute to its success or failure. This information will prove key to developing and implementing computer-based evidence delivery systems in the future.

Step 9. Disseminate the findings and recommendations. /Dissemination strategies depend upon the mission or purpose of the organization sponsoring the assessment. Dissemination should be planned at the outset of an assessment along with other assessment activities and should include a clear description of the target audience as well as appropriate mechanisms to reach them. The costs, time and other resources needed for dissemination should be budgeted accordingly. Dissemination plans do not have to be rigid. The nature of the findings and recommendations themselves may alter the choice of target groups and the types of messages to be delivered. Dissemination should be designed to influence the behavior of relevant decision makers./

New primary studies, new technology assessments, new policy on ICT by increasing relevance and delivery of information to health professionals and health consumers (get information on Health InterNetwork - HIN - United Nations Millennium Action Plan, http://www.healthinternetwork.org /index.php).

Step 10. Monitor impact of assessment reports. /The impact of HTAs is variable and inconsistently evaluated. Plans for monitoring the impact of an assessment report should be considered in the assessment design. Some of the

effects of a HTA report include: acquisition or adoption of a new technology; reduction or discontinuation in the use of a technology; change in behavior; change in the organization or delivery of care; reallocation of national or regional health resources; change in regulatory policy; modification of marketing plan for a technology, … ./. Yet too early to say in this case example.

EXERCISES: Introduction to Health Technology Assessment

Task 1: *Selection and prioritization*

Identify possible health technologies in your country, region or institution that would be worth of assessment.

Define the criteria for prioritization and select the one technology worth assessing.

Task 2: *Planning / policy questions*

Should there be a wish to introduce a public offer of influenza vaccination of the elderly, how should this be organized and what would the effects and costs be?

Task 3: *HTA questions*

Derive HTA questions for influenza vaccination of the elderly keeping in mind that they have to be clearly worded, defined, answerable and limited in number.

Task 4: *Define Project group*

Define complete project management for assessment of influenza vaccination of the elderly.

Task 5: *A HTA is to a large extent based on available evidence*.

List possible sources for any literature review.
Perform a literature review with previously defined search protocol for „Influenza vaccination of the elderly" concerning HTA question - technology: What is the expected survival of the elderly, who are vaccinated against influenza, compared to elderly, who are not vaccinated?

Perform a literature review with previously defined search protocol for „Influenza vaccination of the elderly" concerning HTA question - patient: What do the elderly think of influenza vaccination?

Task 6: *If the literature review didn't give enough scientific documentation there is a need for performing one's own study of the effect of health technology.*

Design studies for HTA questions cited in E2-E5.

- What are possible sources of bias in selected designs? Define advantages and disadvantages in selected designs.
- How would you measure validity in previously designed studies?
- If you choose to measure health status, what type of instruments can you use?

Case problems:

A. Most of the studies on health technology assessment covered new therapeutic and diagnostic health technologies and medical treatments basically concerning economic aspect and medical or patients benefits. This is a common result of few studies realized and published in mid nineties. What is situation today?

B. The inclusion of an unbiased sample of relevant studies is central to the validity of systematic reviews and meta-analysis. Time-consuming and costly literature searches, which cover the grey literature and all relevant languages and databases, are normally recommended to prevent reporting biases. However, the size and direction of these effects is unclear at present. There may be trade-offs between timeliness, cost and the quality of systematic reviews. It seems that there has to be an answer on the question: How important are comprehensive literature searches and the assessment of trial quality in systematic reviews?

C. Telehealth has become widespread in the last two decades in developed countries, despite the generally poor scientific evidence available to support its use. Telehealth, telemedicine, or e-health is defined as the use of information and communication technologies to deliver health services, expertise and information over distance, geographic, time, social and cultural barriers. Telehealth encompasses Internet or web-based „e-health", as well as video-based applications. Applications can be real-time or store-and-forward. How would you provide an information base to assist policy- and decision-makers, researchers and health professionals in their deliberation about telehealth? Provide an overview of the areas of strength and weakness, identify gaps and review policy implications.

D. Screening for gestational diabetes mellitus has been controversial, with some expert bodies advising universal screening, others selective screening, and yet others advising against screening at all. This has partly been a result of debate about the definition of gestational diabetes mellitus, and partly because of the profusion of different tests available, both for screening and definitive diagnosis. In the country X, there is no national policy on screening, and a variety of practices exist in different parts of the country. There have also been doubts about the treatment of gestational diabetes mellitus, and particularly about management of minor degrees of glucose elevation, which are better described as glucose intolerance rather than true diabetes. Provide an updated review of current knowledge, to clarify research needs, and to assist with policy making.

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Recommended Readings

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Comparative Research on Regional Health Systems in Europe**
Module: 1.10	**ECTS (suggested): 0.75**
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Keywords	Health systems, benchmarking, tracer concept, regional health management, measles vaccination, breast cancer screening, European Union
Learning objectives	After completing this module students and public health professionals should have: • explored the methodology of comparative analysis of regional health services in Europe, • received a sound knowledge of 2 selected public health programmes in 4 of 8 European regions, • completed an analogous analysis of their region of origin.
Abstract	Because of the rapid changes and in search for cost-efficiency, quality and professional excellence, the health systems in Europe are undergoing comparative analysis tends to focus on selected services in defined sub-national regions in order to obtain relevant information for benchmarking. In this module 2 programmes (measles vaccination and breast cancer screening) are described in detail for 8 European regions according to defined categories.
Teaching methods	Teaching methods include an introductory lecture based on the introductory module, students' individual work under the supervision of teacher and interactive methods such as small group discussion. After the introductory lecture students will work individually or in teams of 2 or 3 on the exercises, each followed by a small presentation and discussion with the full group.
Specific recommendations for teacher	It is recommended that the module should be organized within 0.75 ECTS credits, out of which one third will be done under supervision, while the rest is individual student's work. Teacher should advise students to use as much as possible electronic libraries during individual work to gather ideas how to write and present their own case problems.
Assessment of Students	Individual presentation and group reports.

COMPARATIVE ANALYSIS OF REGIONAL HEALTH CARE SYSTEMS IN THE EUROPEAN UNION

Birgit Cornelius – Taylor, Ulrich Laaser

In the European Union the health sector until very recently remained exclusively a national domain. However repeated decisions of the European High Court during the last years made clear that health services are to be considered as subject under the so-called Four Freedoms (full mobility of persons, goods, services and capital within the European Union) even though the health market is not an unrestricted competitive market (1). This means e.g. that in the future patients can ask for medical services throughout the EU and will be covered by their health insurance or other payment mechanisms at home. An electronic health insurance card is presently tested and will be introduced in 2004-06. In the public health field this harmonisation of inherited national structures is even more advanced, very much enhanced by the treaties of Maastricht and Amsterdam with their articles on the public health mandate of the European Commission acc. to Article 129 resp. 152 (2).

All health systems in Europe are presently under reform, be it in the western states because of the need to curb costs especially for the employers in order to remain competitive in a globalising world economy, or be it in the eastern states regarding the transition from the prior socialist system to a modern one, usually a mix of Beveridge and Bismarck elements. This makes a comparative analysis difficult because of the frequent legislative changes as well as because of the emergence of regional solutions, e.g. in the so-called Euro-Regions in border areas between member states (foremost between Germany, France and Benelux but developing also between Germany and Poland).

It is against this background that analysts prefer to concentrate on selected services as so-called tracers in defined regions to establish valid comparisons which can be used for benchmarking or measuring relative performance for a selected set of defined criteria (e.g. 3). For the following analysis preference has been given to the public health aspects and to this purpose measles immunisation programmes and breast cancer screening programmes have been chosen in selected countries and regions (Table 1). The descriptive part is taken with permission from the EU-Project „Benchmarking Regional Health Management Ben RHM" (4).

Table 1. Comparative Analysis of Regional Health Care Systems

No.	**Country**	**Region**
1)	Austria	Upper Austria
2)	**Czech Republic**	**Moravian-Silesian Region**
3)	United Kingdom	England
4)	Greece	Western Greece
5)	**Germany**	**Northrhine-Westphalia**
6)	**Ireland**	**Eastern / Midland / North-Eastern Regions**
7)	**Italy**	**Veneto**
8)	Sweden	Stockholm

For a comparative analysis specific categories are employed (Table 2):

Table 2. Analytic Categories for Regional Comparison of Preventive Health Care

No.	**Category**
1	**Demography**
2	**Organisation and Structure of the Regional Health System**
3	**Measles Immunisation Programmes**
3.1	Organisation of programmes
3.2	Vaccination strategy
3.3	Information and education
3.4	Programme related projects/campaigns
3.5	Vaccination documentation and data collection
3.6	Programme monitoring and evaluation
3.7	Disease surveillance
4	**Breast Cancer Screening Programmes**
4.1	Screening strategy
4.2	Dissemination of results
4.3	Information and education
4.4	Programme related projects/campaigns
4.5	Programme monitoring and evaluation
4.6	Disease surveillance

Of the 8 regional reports listed in Table 1 the following 4 are made available below.

2) Moravian-Silesian Region – Czech Republic

2.1 Demography

Moravia-Silesia is one of 14 regions in the Czech Republic with about 1.26 million of the country's roughly 10 million inhabitants. 0.62 million of the inhabitants are male and 0.65 million female.

The region lies in the eastern part of the country, which shares borders to Poland and Slovakia, and is divided into six districts. Moravia-Silesia covers an area of 5 554 km^2 with a population density of 234 inhabitants per km^2.

2.2 Organisation and structure of the health system

The health system in the Czech Republic has undergone several changes and reforms, some of which are still ongoing. Decentralisation of the health care system (mainly focused on ambulatory services) is a major feature of the reforms, but its implementation is not yet complete. The task of health care has been delegated to health insurance funds, which are under the supervision of the state.

The Ministry of Health is responsible for the preparation of health care legislation, health and medical research, for the licensing of pharmaceuticals and medical technology and for the management of two institutes for postgraduate education and training of health professionals. It also organises the joint negotiations concerning the list of services covered by health insurance which serves as the fee schedule. The Ministry directly manages regional hospitals, university hospitals, specialised health care facilities and institutions for research and postgraduate education.

Following the dissolution of both the district institutes of national health and the regional institutes of national health, state health administration was incorporated into the district authorities in the form of health offices headed by district health officers. The district health officers are under the direct supervision of the Ministry of Interior Affairs, whilst the Ministry of Health provides methodological guidance and supervision. The district health officers are, however, legally responsible for ensuring that accessible health services are provided in their areas.

In line with recent reforms, hygienic services (public health services) no longer exist at the district level. The whole system is now based at the regional level, with the regional public health institutes being responsible for public health in the whole region. These institutions are responsible for

epidemiological surveillance, immunisation logistics and safety measures concerning environmental hazards, food and other areas (European Observatory on Health Care Systems 2000a).

2.3 Measles immunisation programmes

Immunisation programmes are generally covered by the national legislation within the Public Health Protection Act from the year 2000. The provision of immunisation by the responsible organisations is obligatory and parents have to have their children immunised against diseases covered in the child immunisation programme. The state is responsible for the welfare of children and youth up to the age of 21 and has the right to force parents to have their children immunised.

The routine obligatory vaccination against measles started in 1969 in the Czech Republic. A two doses strategy was introduced in 1974.

Organisation of programmes

The Ministry of Health together with the public health institutions at regional level plans the national immunisation programmes.

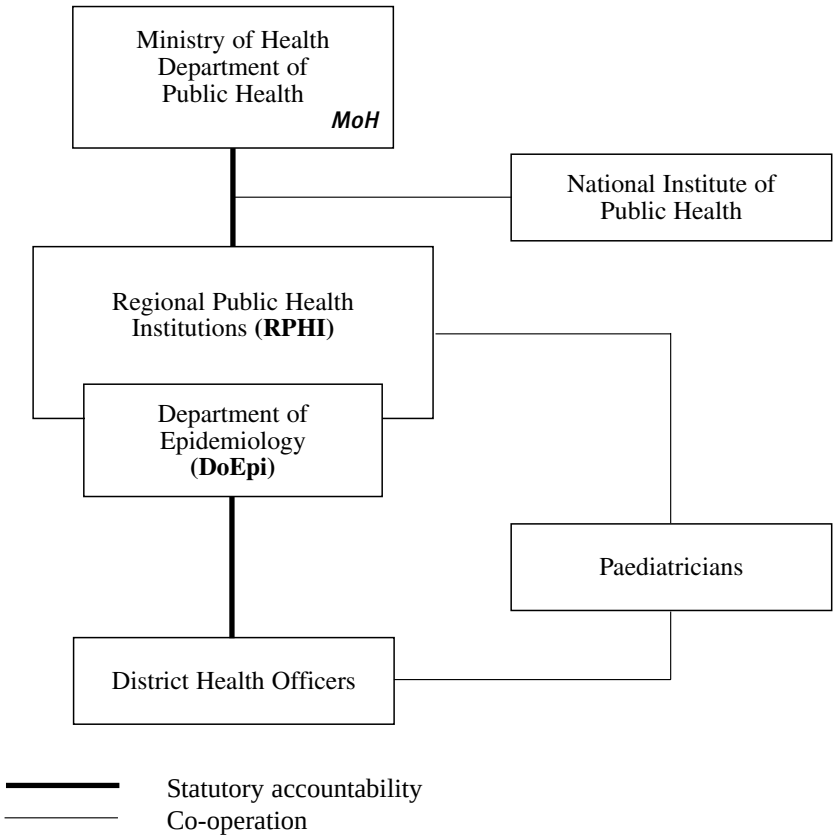
The National Institute of Public Health, which falls under the Department of Public Health in the Ministry of Health, in co-operation with regional public health institutes prepared a national public health policy which includes the targets of the immunisation programmes.

Regional measles immunisation programmes are part of the national immunisation programme and are basically organised similarly in all regions.

Regional immunisation programmes are drawn up by district public health officers who prepare the programmes to reflect the national policy. The programmes are financed from the national budget via the regional public health institutes. The Department of Epidemiology in each regional public health institute is responsible for the implementation of the measles immunisation programmes.

Paediatricians, in their role as primary health care providers are responsible for preventive services such as immunisation and co-operate with the public health institutes at both regional and district level (Figure 1).

Figure 1. Organisation plan for the measles immunisation programme in Moravia-Silesia



Vaccination strategy

The two dose MMR vaccine is carried out with the first dose being given at 15 months and the second at 21-25 months of age. The MMR vaccine was introduced in the Czech Republic in 1996, prior to which a local vaccine called MOPAVAC Divacine had been given.

The Moravian-Silesian region has a special computerised system, ISID (Information System for Immunisation of Children) which it uses to invite and remind parents to take their children for vaccination. This system is not used by all other regions in the country.

At birth, each child is registered, and allocated a paediatrician by the respective district public health institute, which forwards the information to the Regional Public Health Institute. The Regional Public Health Institute maintains a register of all children in the region and their respective

paediatricians. When a particular vaccination is due, the regional institute sends a letter of invitation to the parents, giving information about which inoculation is necessary and their appointment at the paediatrician. The paediatrician is informed of those children required to attend for vaccination on a particular day and is expected to inform the regional Public Health Institute of available appointments for the administration of vaccinations. In the case of non-attendance, the paediatricians send a reminder to the parents. Should the child still not attend, the Regional Public Health Institute then explains the importance of the vaccination to the parents.

Two of the 6 districts in the region do not have the computerised system and the paediatricians there have to organise the invitation of parents themselves. The invitation system run by the regional office is financed by the municipality in Ostrava, where the office is located.

The Ministry of Health provides each region with vaccine, which is distributed as necessary to the district public health institutes, from which paediatricians order their vaccines. The Regional Public Health Institute is responsible for checking that appropriate conditions are maintained for the storage of vaccines.

Information and education

Although no systematic measurement of public opinion has been undertaken, the measles vaccination programme is generally considered to be good and well accepted.

Public health authorities organise special training workshops for paediatricians in the districts once or twice a year. The participation is voluntary and carried out by the health insurance companies and medical board.

Programme related projects/campaigns

At present there are no campaigns or projects related to measles immunisation being organised. The measles uptake rate is very high for both the first and second doses of MMR and the region of Moravia-Silesia has had no measles incidence in the past 4 or 5 years.

Vaccination documentation/data collection

There are three levels of vaccination documentation in Moravia-Silesia, two of which are country-wide. It is the duty of the paediatrician to record the date, type and batch number of the vaccine given in the child's medical record. Secondly, the paediatrician has to enter the vaccination details on the child's vaccination certificate, which is held by the parents. The third form of documentation, which is only regional involves the computerised documentation of the vaccination details. The paediatrician returns the list of children he/she received from the Regional Public Health Institute, having marked the children who attended. Information such as vaccination coverage of children of a particular age can be obtained from the computerised system for any chosen period or point in time.

Paediatricians also check the immunisation of their patients in the vaccination certificates during each medical or preventive examination.

Disease surveillance

Together with the introduction of the obligatory measles vaccination programme in 1969, a national surveillance system for measles was introduced.

The National Institute of Public Health in Prague is responsible for the national surveillance of measles in the Czech Republic; there are two national reporting systems, one for all infectious diseases in the country and one covering vaccine related complications.

Annual reports on the data are published in print form and on the internet.

2.4 Breast cancer screening programmes

A professional breast examination programme has been included in the Czech National Oncological Prevention Programme since 2002. GPs and gynaecologists carry out breast examination as part of preventive examinations offered to women between 45 and 69 years of age every two years.

There are no special campaigns, information events or projects held in relation to professional breast examination, as the participation in the oncological prevention programme is assumed to be quite high, though dependant on educational and social background.

Breast self examination has been part of the national public health promotion agenda for a long time. Although strictly speaking no programme

exists, a lot of information (pamphlets, brochures, booklets, posters) have been published and distributed to the public in general. Discussions are held in schools and clinics and GPs and gynaecologists discuss the issue with their patients.

Mammography screening programmes are in the process of being implemented in some parts of the Czech Republic. In the Moravian-Silesian region, the programme officially started on the 2nd of September 2002 and up to the end of March 2003, eight screening units were involved, four of them based in Ostrava, the regional capital city. At this time, there are 49 accredited screening units nation-wide.

Organisation of programmes

The mammography screening programme was suggested by physicians, who felt the need to have a proper screening methodology for the population. Endorsed by the Ministry of Health, a national committee consisting of radiologists and other specialists was established with the responsibility of accrediting and organising quality assurance checks of the workplace-units. Each unit must conduct a minimum of 5000 mammographies per year and fulfil the technical requirements to achieve and maintain accreditation.

Although health insurance companies are not directly involved in the organisation and implementation of the screening programmes, the accredited screening units negotiate directly with health insurance companies over finances.

Even though national meetings are organised for all screening units within the mammography screening programme, no real co-operation amongst units in the same region is evident.

Screening strategy

The screening programme is targeting women in the 45-69 years age-group. Since no invitation system operates in the Moravian-Silesian region, patients are referred by their gynaecologist or GP. Following their first appointment the unit's computer uses the stored patient data to generate invites for repeat checks. At the initial attendance, women are requested to complete questionnaires on family risk factors, breast self-examination experience and results, hormonal therapy and general medical history.

Dissemination of results

The national screening programme recommends that mammograms are to be read by two experienced radiologists whilst the patient is waiting, and results given out immediately. This is however not always possible, as some units do not have the necessary number of radiologists to do this, in which case, the results are sent to the referring physician within three days of the mammogram. Should the mammogram be unclear or abnormalities are seen, the woman is invited for further assessment.

Information and education

A lot of publicity, mainly through the popular media, has accompanied the establishment of mammography screening programmes. This, together with the recent rising interest of citizens in matters concerning their health, has led to a lot of interest from the public in general and women in particular. Women in Moravia-Silesia have been known to go to their gynaecologist and request to be referred for mammography screening. Gynaecologists, thus, find it easier to convince their patients of the necessity of the screening procedure. One problem, which still has to be solved, is that of how to approach and also raise the interest of women with low educational backgrounds and/or from the lower social class.

Information events are also organised for gynaecologists where they are informed about the aims and objectives of the programme. Further education / training courses and meetings are also organised for radiologists and other professions involved in the programme.

Programme monitoring and evaluation

In Moravia-Silesia no programme evaluation has been conducted up to date, as the programme itself is still quite young; it is however, planned on an annual basis. The national committee responsible for accreditation of units will inspect all units yearly and the accreditation will be renewed annually. The success of the screening programme will be measured using determinants such as attendance rates, cancer detection rate and further assessment referral rate.

Disease surveillance

Cancer registration is maintained nationally by the Institute of Informatics and Statistics in Prague. All gynaecologists and physicians are bound by law to report all cases of cancer diagnosed to the nearest public health authority at the district or regional level. The public health authorities

then forward the information to the Institute of Informatics and Statistics for entry into the national cancer registry.

5) North Rhine-Westphalia, Germany

5.1 Demography

North Rhine-Westphalia (NRW) is one of the 16 German federal states with a total population of 18 million inhabitants. This corresponds to about 22% of the German population. It covers an area of 34,080 km^2. With 530 persons per km^2, NRW's population density is more than twice as high as the German average.

Further demographic characteristics of the state of NRW are as follows:

Males: **8.82 million (49%)**
Females: **9.18 million (51%)**

Of the almost 880,000 inhabitants of the age group 0-4 years, 450,000 are males and 430,000 females.

The female population of the age groups 50-69 years targeted for mammography screening (a total of 2.13 million) can be broken down into the following categories:

Age group in years	**Number**
50 – 54	470,000
55 – 59	490,000
60 – 64	590,000
65 – 69	580,000

With 2 million people, NRW's migrants account for about 11.4% of the state's population.

5.2 Organisation and structure of the health care system

Germany is a federal republic with 16 federal states, and each of them has its own constitution which is in accord with the German Federal Constitution. The sharing of decision-making powers between federal and state level is a fundamental aspect of the political system and thus also of the health system. The German health care system is primarily characterised through the development of health insurance funds. The statutory health insurance system (GKV), which was set up under the Federal Government's social legislation scheme, provides insurance protection for about 90% of Germany's citizens since GKV membership is obligatory for employees up to a fixed income level.

In addition to the health insurance funds as financing bodies on the one hand, Germany's health care system is characterised through its doctors, dentists, pharmacists and hospital organisations as service providers on the other hand. Like health insurance funds they are organised as public corporations and/or associations and perform their tasks as self-administered bodies, i.e. within the framework of federal government regulations and supervision they are authorised to perform all functions under their own responsibility.

The Federal Government defines the organisational structure of the self-government system through legislation and decrees in the Social Codes (above all Social Code V).

At regional level, the German states are responsible for hospital planning, hospital investments and for the public health service. For these areas they have their own decision-making powers but also the possibility to exert influence on the governments' statutory health insurance legislation through their representatives in the German Bundesrat.

5.3 Measles vaccination programmes

Before the reunification of the former GDR and West Germany in 1990, both countries differed considerably in their approaches to measles surveillance, vaccination strategies and the provision with vaccines. The former GDR had a highly centralised health system. In 1970, the voluntary single measles vaccination, which had been introduced in 1967, was made obligatory by law for children aged 8 months or older. The public health service played a central role in the implementation and registration of the vaccination. In 1986, a second vaccination was introduced as a matter of routine 6-12 months after the first vaccination. In the Federal Republic of Germany, measles vaccination was generally carried out on a voluntary basis and recommended for infants aged 12 months or older. In 1980, the combined measles, mumps, and rubella vaccination was introduced, with a recommended second vaccination from the year 1991 onwards. After the German reunification, this practice was also adopted for the states of the former GDR.

Organisation of vaccination programmes

The legal basis for the prevention and fighting of infectious diseases – among others also for protective vaccinations – in the Federal Republic of Germany is the Infectious Disease Control Act (IfSG) which entered into force on 1 January 2001. Under this Act obligatory notification of measles cases was introduced for the first time all over Germany and the health departments were obliged to ascertain the vaccination status of children during school entrance examinations. Up to that time, the vaccination status had been identified during school entrance examinations in NRW on a voluntary basis.

There is no compulsory vaccination in the Federal Republic of Germany. Recommendations for vaccinations are worked out in accordance with state-of-the-art-knowledge by an expert committee, the Standing Vaccination Committee (STIKO) of the Robert-Koch-Institute in Berlin. The list of vaccinations recommended by STIKO comprises standard vaccinations for infants, children, adolescents and adults including the recommended age at which the vaccination should be taken and the minimum intervals between the vaccinations.

The individual German states decide for themselves whether they will adopt these recommendations without any changes. In NRW, the correspondingly latest STIKO recommendations are regarded as official recommendations.

The individual German states also decide for themselves about the planning and implementation of vaccination programmes as well as about their main focuses. Vaccination programmes can be carried out both at state and local level, as single actions or as concerted actions.

The WHO target to eliminate measles by the year 2007 is explicitly supported by the Federal Republic of Germany. So at the 71st Health Ministers' Conference (GMK) in 1998, the responsible health ministers and senators decided to take concerted measures for the combat of measles together with the Federal Government, the public health service (ÖGD), the health insurance funds, the chambers of physicians and further partners. Participation in measles' vaccination programmes shall be considerably increased and the incidence of measles reduced by 90% in Germany within the next years.

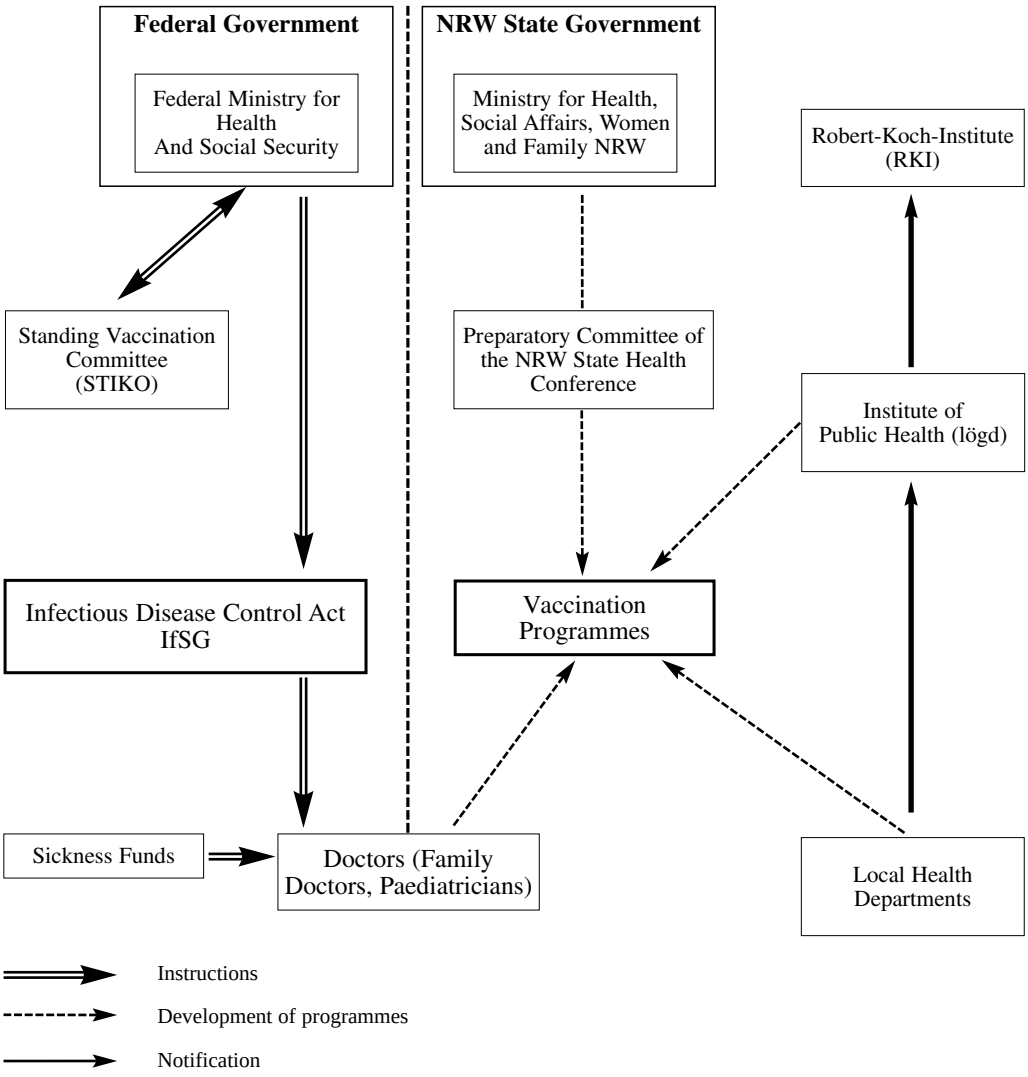
In a move to implement this resolution, an action programme for the prevention of measles, mumps and rubella was adopted at NRW's 10th State Health Conference which includes all major actors involved in NRW's health care sector. Members of this body are representatives of the chambers of the medical care professions, associations of panel doctors, social insurance funds,

hospital society, charitable organisations, self-help initiatives, trade unions, employers' associations and of the public health service.

This action programme in NRW provides for various measures at different levels (state and local level) which support and supplement each other.

The different organisations and authorities which are involved in implementing the measles' vaccination programmes in NRW as well as the levels at which they act, can be taken from the following organisation plan (organograph) below (Figure 2).

Figure 2. Organisation plan for the measles immunisation programme in North-Rhine Westphalia



Vaccination strategy

Recommendations for a first and second measles, mumps and rubella vaccination have been in force for Germany since 1991. In its July 2001 recommendations, STIKO supports the first MMR vaccination for children between their completed 11th and 14th month of life and the second between their completed 15th and 23rd month of life. Missing vaccinations should be received by the 18th year of life at the latest.

Vaccinations are given following consent from the parents/legal guardians who also have the right to opt against vaccination for their children. There is no automatic invitation or reminder system for vaccination attendance. At the birth of their children, parents are issued with a vaccination card together with a child health record booklet which they should bring with them each time they see their doctor. Parents learn about the STIKO recommendations from a vaccination plan they can get from their paediatrician, family doctor or from the sickness funds. Thus it is in most cases within the responsibility of the parents to survey and observe these deadlines and to make the required appointments with their paediatrician or family doctor. The vaccinations are mostly carried out by the paediatrician or family doctor in his/her practice rooms. Doctors order the vaccines from pharmacies and forward their claims to the statutory health insurance funds (GKV) via the association of panel doctors.

Information and education

Parents/legal guardians are amongst others also informed about the procedure and necessity of measles vaccinations when they see their paediatrician or family doctor. Another opportunity for information is provided by the school entrance examination, which is carried out by the medical staff of the health departments.

Surveys in Germany have shown that the doctor's advice is paramount in influencing the decision for vaccination. Information campaigns on vaccinations therefore regularly include doctors and physicians.

The latest STIKO recommendations are conveyed by the Federal Chamber of Physicians to the chambers of physicians at state level which then inform the doctors. At the same time doctors are informed through publications in the corresponding medical journals or through additional vaccination seminars which are organised by the chamber of physicians.

To inform the population about vaccinations, North Rhine-Westphalia uses various methods. These include the telephone announcement service of the Ministry for Health, Social Affairs,Women and Family (MGSFF). Under a service telephone number interested citizens are informed at two-week intervals about topical issues from the health care sector through the announcement service. This also includes an announcement text on vaccinations. Through publications from the press release office of the MGSFF, the population in NRW is also informed about this issue. Moreover, MGSFF has also issued its own flyer on measles, mumps and rubella which can also be used by the health departments in NRW for vaccination campaigns.

For local vaccination campaigns, the health departments turn directly to the regional media (e.g. local press, radio stations) and issue their own press releases.

Health insurance funds use their magazines to inform their members at irregular intervals.

Programme-related projects/campaigns

The Action Programme for the Prevention of Measles, Mumps and Rubella adopted by the 10th State Health Conference in August 2001 is aimed at a permanent increase in vaccination levels among children and adolescents in NRW. The background are the presently still high incidence figures particularly for measles as well as the risk potential resulting from inadequate vaccination levels against mumps and rubella.

Activities at state level

For the planning, coordination and implementation of supra-regional vaccination programmes, NRW has the Institute of Public Health NRW (lögd) at its disposal. In addition to its functions stipulated in NRW's legislation as a „public health coordination centre" and „official NRW authority for the surveillance of infectious diseases" (in accordance with Sec 11 Infectious Disease Control Act) the management of local vaccination data through the lögd as a service provider supplements the requirements for this function. The list of measures conceived by the lögd is aimed at abolishing deficits in knowledge, motivation and implementation of the vaccination idea both within the population and in the health sector. Important single measures of this campaign are the early identification of the vaccination status as early as at kindergarten entrance, improved vaccination information campaigns in schools and companies, improved qualifications of those working in the health sector, the targeted improvement of vaccination levels by sending a mobile vaccination unit to the municipalities as well as a continuous evaluation and publishing of the activities carried out. Important partners during implementation phases are in particular the local health conferences as well as the health departments in the municipalities.

Activities of the local health conferences

An important body for the discussion and implementation of measures also with regard to protective vaccinations in NRW are the local health conferences. Members are health care actors involved in health promotion and health care for the population, self-help groups and institutions for health care

and patients' rights protection as well as members of the council or district assembly responsible for health. Together, as an independent body, the local health conferences deliberate on various thematic topics and questions of interest in health care at the local level with the objective of coordinating them and if required give recommendations for action. These recommendations are implemented under the self-commitment of the actors involved. These agree joint solutions at the local level and initiate their own actions such as for example actions for the prevention of measles, mumps and rubella.

To support these activities, the lögd has developed a planning programme for MMR.

Activities of the individual health departments

There are 54 health departments in NRW which are part of the local self-government system. As implementation level of the public health service, they are among other things responsible for important tasks pertaining to hygiene control and the promotion of health protection at population level. In addition to the identification of the vaccination status at school entrance examinations, these tasks also include vaccination activities which are based on recommendations for action given by the local health conferences or which can be decided by the health departments themselves. They are primarily guided in their actions by the principle of respecting the subsidiary sharing of tasks according to which the implementation of officially recommended regular vaccinations primarily falls within the responsibility of practising doctors and measures of the public health service should only be aimed at improving vaccination levels.

Vaccination documentation/Data collection

In accordance with the Infectious Disease Control Act (IfSG), the vaccinating doctor is obliged to register every protection vaccination on a vaccination card or, if it has not been submitted, to issue a vaccination certification. The kind of data to be documented is also fixed in the Infectious Disease Control Act.

There are no further documentation methods such as for example a vaccination register.

The vaccination status of children is identified during school entrance examinations which are required for school entrance. All children and/or their accompanying parents are requested but not forced to bring the vaccination card. For NRW figures from the year 2000 show that of 137,284 children who

had participated in the school entrance examination and had been issued with a vaccination card almost 90% had received the first MMR vaccination but only 14% the second vaccination.

As stipulated in the Infectious Disease Control Act, the health departments are obliged to transmit vaccination data collected during school entrance examinations in an anonymised and aggregate form to the Robert-Koch-Institute via the superior state health authorities. The Institute of Public Health annually publishes the data available from school entrance examinations in NRW and thus also the vaccination data.

Disease surveillance

With the entering into force of the Infectious Disease Control Act on January 1st 2001 all clinically and laboratory-confirmed measle cases were made notifiable in Germany.

The Infectious Disease Control Act stipulates that independently from each other both the attending doctor and the confirming laboratory are obliged to report the name of the measles patient. The task of putting both kinds of information together into one case and if necessary to conduct further inquiries falls within the responsibility of the health department. The notification deadline of 24 hours and the extent of facts and information to be notified are also stipulated by law.

This process has to be distinguished from the notification procedure from the health department to NRW's state authorities and RKI. It differs from the above-described procedure both with regard to the extent and deadline of the notification. In accordance with Sec 11 of the Infectious Disease Control Act, anonymised data have to be transferred to NRW's state authority by the third working day of the following week after the health department has received the notification. The state authority again has to transfer the data within one week to the RKI. The responsible state authority at the lögd is charged with the tasks of pooling, quality control and surveillance of the notifications they receive from all 54 districts and/or self-administered cities in NRW. This also includes publishing the information on the Internet without delays to ensure a backflow of information as part of a closed data cycle. At federal level, the same tasks are performed by the Robert-Koch-Institute. With the publication of the data in the „Epidemiologisches Bulletin", on average about 3 weeks after having registered the notification, the data are given official character.

To complement this routine notification procedure, in October 1999 a measles sentinel for the continuous and immediate registration of measles

cases was set up at the national level. In this study called „Arbeitsgemeinschaft Masern" (AGM) about 1.200 physicians, in most cases paediatricians, on a voluntary basis collect data on the seasonal, regional and age-specific distribution of measles in Germany. Of special importance are data which can only be gained through this – from the IfSG notification procedure – independent system on the individual development of the disease, on the precise vaccination status and on the results of comprehensive laboratory diagnoses. The latter in particular provide indisputable contributions to assessing the effectivity of the vaccination.

Both registration systems, which presently exist simultaneously, ensure good national surveillance as a prerequisite for the further systematic fighting of measles with the objective of their eradication.

5.4 Breast cancer screening programmes

Medical breast examinations are carried out throughout Germany based on the Early Cancer Detection Act contained in Social Code V in accordance with the guidelines of the German national doctors' and sickness funds' associations. They are part of the annual cancer screenings which are offered to all women aged 30 years and/or older and include palpation of the breast and lymphatic nodes and an instruction for breast self-examination.

In the case of suspicious palpation findings further steps are taken in cooperation with the correspondingly specialised diagnosis and treatment centres.

Both sickness funds and panel doctors' associations as well as organisations for the combat of cancer at the regional level and self-help groups are involved in informing the public about screening programmes which include breast examinations.

Breast self-examination

In the same way there is no programme for breast self examination. Women take their instructions from flyers or brochures they get from their gynaecologists or from information campaigns.

According to NRW's health ministry, less than 50% of the women take part in cancer screening programmes in North Rhine-Westphalia. To encourage women to take part in these examinations which are generally paid by the sickness funds, in 2001 NRW launched an intensive campaign against breast cancer. The campaign was carried out by various organisations in NRW including

chambers of physicians, hospitals, sickness funds and cancer organisations. It encouraged women to examine their breasts and called upon doctors to provide the corresponding instructions. In addition, more than 300 seminars on breast self examination are each year organised throughout the state of NRW.

Similar to the medical examination of the breast, breast self-examination plays an important role for cancer prevention because a great number of women consult their gynaecologist after having discovered an irregularity. This also applies to women who perhaps would normally not participate in cancer screening programmes.

Mammography screening programmes

Mammography screening programmes are presently still in their initial phase of initiation in Germany. The precise conditions and regulations according to which the programmes are to be carried out are presently being established in accordance with the European guidelines for quality assurance of mammography screenings (EUREF). This concerns the technological and qualitative standards to be fixed for the institutions in which mammography screenings will be carried out. Mammography pilot programmes, which were carried out between 2001 and 2002 in the three regions of Bremen, Weser-Ems and Wiesbaden, serve to introduce blanket coverage with screening programmes which cannot be achieved before 2005.

They were carried out following international standards such as the European guidelines for quality assurance of mammography screenings. In a special invitation letter all women between 50 and 69 years of life are called upon to participate in the programmes. The programme is aimed at a high participation rate, attaches considerable importance to interdisciplinary teamwork and ensures high quality standards in accordance with EUREF.

6) Eastern / Midland / North-Eastern Regions – Ireland

6.1 Demography

The Eastern Regional Health Authority (ERHA) with its three constituent Health Boards, and the Midland and North-Eastern Health Boards respectively, cover the combined Eastern, Midland and North-Eastern regions.

The Health Boards Executive (HeBE) was established in February 2002 to enable Health Boards, the Eastern Regional Health Authority and non-statutory provider agencies to work together on an agenda to develop and modernise the health delivery system. The Board of HeBE is comprised of the Chief Executives of the Health Boards and the ERHA and also has representation from the Chief Executives of the Dublin major teaching hospitals.

The demographic characteristics of the combined three regions are as follows:

Male population: **0.89 million**
Female population: **0.92 million**

Of the 126,800 inhabitants in the 0-4 years age-group 65,400 are male and 61,400 are female.

The female population in the age-group targeted by mammography screening programmes is divided as follows:

Age group in years	**Number**
50 – 54	46,000
55 – 59	38,100
60 – 64	34,000
total	118,100

(1996 Census of Population)

6.2 Organisation and structure of the regional health system

Health services in the Republic of Ireland are financed through general taxation, with funding for programmes being provided to the Health Boards by the Department of Health and Children.

The description of the structure and organisation of the Irish health system, which also applies to the Eastern Regional Health Authority with its three area Health Boards, is taken from „Quality and Fairness", a paper of the Department of Health and Children explaining the New Health Strategy 2001:

"*The Government, the Minister for Health and Children and the Department are at the head of health service provision in Ireland. The Department's primary role is to support the Minister in the formulation and evaluation of policies for the health services. It also has a role in the strategic planning of health services in consultation with health boards, the voluntary sector, other government departments and other interests. The Department has a leadership role in areas such as equity, quality, accountability and value for money.*

The health boards, established under the Health Act, 1970 are the statutory bodies responsible for the delivery of health and personal social services in their functional areas. They are also the main providers of health and personal social care at regional level. Health boards are composed of elected local representatives, ministerial nominees and representatives of health professions employed by the board. Each health board has a Chief Executive officer (CEO) who has responsibility for day-to-day administration and is answerable to the Board. The Health (Amendment) (No. 3) Act, 1996 clarified the respective roles of health boards and their CEOs by making boards responsible for certain reserved functions relating to policy matters and major financial decisions and CEOs responsible for executive matters. In addition, many other advisory, executive agencies and voluntary organisations have a role to play in service delivery and development in the health system." (Department of Health and Children 2001)

As regards the Health Boards within the combined Eastern/ Midland/North-Eastern regions, their main role can be considered as the planning, arranging, co-ordination and delivery of health and personal social services in the region in co-operation with the local voluntary service providers.

6.3 Measles immunisation programmes

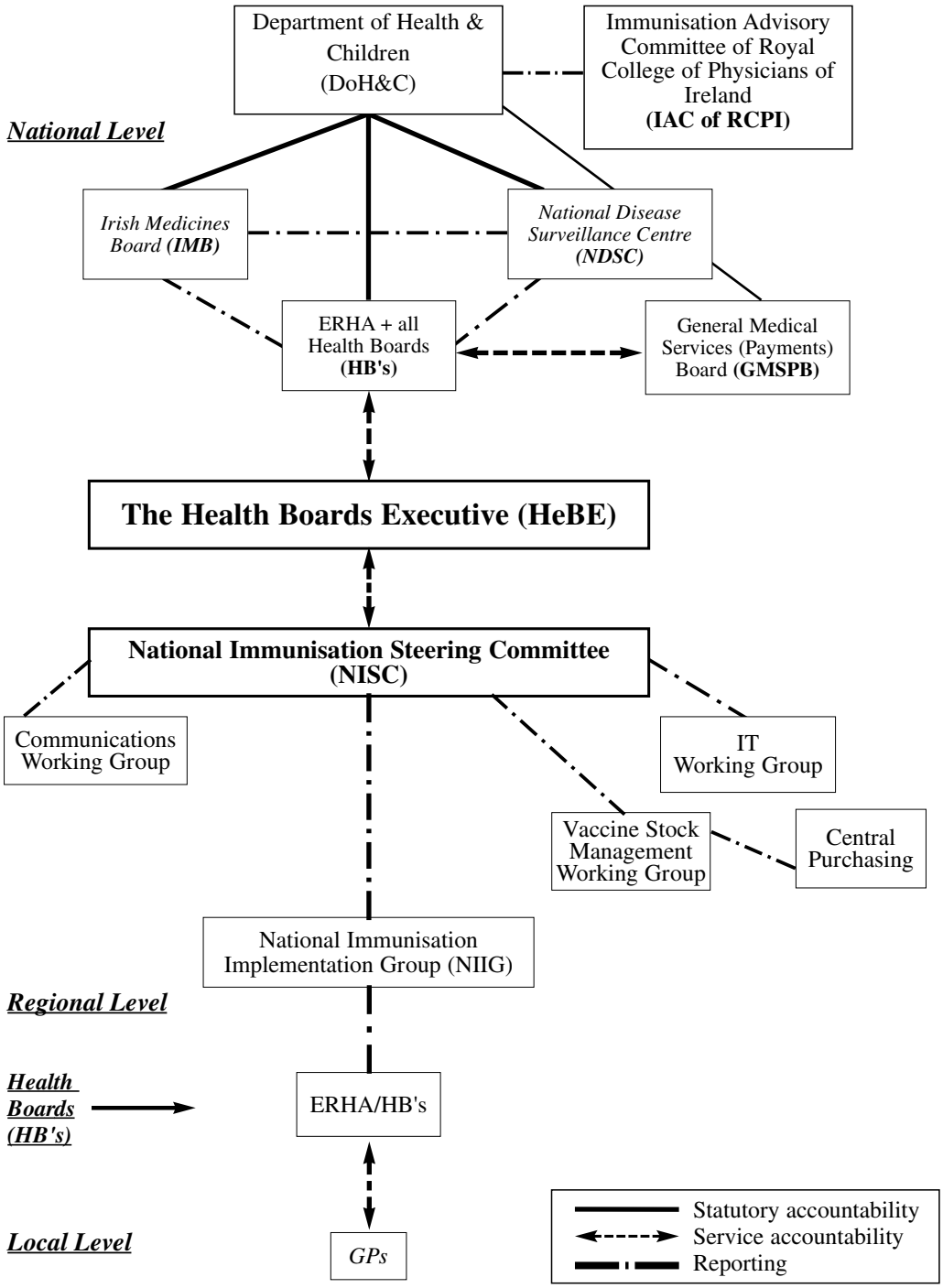
Measles vaccination was introduced country-wide in 1985; the combined MMR vaccine was introduced in October 1988. In 1992, a second dose of MMR was recommended for boys and girls aged 10-14 years. The introduction of measles vaccine and the combined MMR vaccine has led to a decrease in the numbers of measles notifications. However, the uptake of MMR in Ireland has not yet reached the target of 95% and outbreaks continued to occur in 1993 and 2000 (The Health Boards Executive 2002a). Therefore the Health Board Chief Executive Officers initiated a „Review of Immunisation/ Vaccination Programmes" which was to examine the policy, practice and procedures of all immunisation/vaccination programmes. An increasing emphasis on the need to improve the uptake of immunisation/vaccination programmes e.g. MMR, and the increasing public and media discussion of immunisa-

tion/vaccination issues such as vaccine safety were part of the background against which the review was established (The Health Board Executive 2002b).

Organisation of programmes

The different organisations and agencies involved in the realisation of measles immunisation programmes as well as the levels at which the programmes are planned and co-ordinated are illustrated in the organisation plan below (Figure 3).

Figure 3. Organisation plan of the measles immunisation programme for Eastern/Midland/North-Eastern Regions



Department of Health and Children (DoH&C):
- formulates immunisation targets on advice of **IAC of RCPI**
- decides on programme policy and funding (financing is through general taxation)
- provides **HB's** with funding for immunisation programmes
- together with **HB's,** is responsible for health education in general

Immunisation Advisory Committee of Royal College of Physicians of Ireland (IAC of RCPI):
- draws up guidelines and advises on targets for measles immunisation programme based on WHO and other international guidelines

Irish Medicines Board (IMB):
- decides on licences and conditions of use of vaccines and monitors adverse reactions to vaccines

Health Boards Executive (HeBE):
- co-ordinates the planning and implementation of immunisation programmes with HB's at regional level
- facilitates a co-ordinated national response involving all key actors e.g. HB's, DoHC, NDSC, IMB etc.
- together with HB's, is responsible for specific information on immunisation programmes and actions
- together with HB's and DoHC, is responsible for national promotion and public information campaigns on immunisation
- informs NISC of matters of common operational or policy significance discussed with HB's

National Immunisation Steering Committee (NISC):
- is a newly established body representative of all key interest groups dealing with immunisation in general
- under the aegis of **HeBE**, co-ordinates activities of measles immunisation programme at national level
- will in future address the evaluation of projects or campaigns relating to measles immunisation

National Immunisation Implementation Groups (NIIG):
- acts as a practical coordinating mechanism between NISC and Health Boards, as each Health Board is represented on NIIG by its Regional Immunisation Coordinator
- provides feedback and policy advice to NISC

National Disease Surveillance Centre (NDSC):
- evaluates immunisation programmes at national level (monitors vaccine uptake and incidence of disease)
- analyses data from all Health Boards and publishes quarterly reports

Health Boards (HB's):
- responsible for planning and implementation of immunisation programmes
- order vaccine from supplier and distribute them to GP practices and other required locations
- implement special campaigns or projects relating to measles immunisation at regional level
- are responsible for regional surveillance and for documentation of vaccines given
- primarily responsible for operation of call/recall systems

General Medical Services (Payment) Board (GMSPB):
- pays GPs for immunisation services provided on behalf of HB's

General Practitioners (GPs):
- provide immunisation services and have responsibility to identify children who have been immunised and to follow up defaulters
- maintain records of children immunised and forward immunisation and/or disease data to HB's and to DoH&C as required
- responsible for updating their knowledge on immunisation and to promote childhood immunisation

Vaccination strategy

In accordance with the RCPI guidelines, two doses of MMR have been recommended in the Republic of Ireland since 1992, with the first dose being given at 12–15 months of age and the second at 4–5 years of age. Parents are personally invited to bring their children for vaccinations and this is occasionally supplemented by public information through the media.

Vaccine procurement is organised centrally by the HeBE and it is distributed directly from the supplier to each Health Board in the quantities requested by them. It is then distributed to GP practices and to other required locations for use in schools or special clinics. A new system of direct distribution from supplier to end user is being piloted in order to shorten the supply chain and to better avoid any vaccine deterioration e.g. due to storage at sub-optimum temperatures.

Individual immunisation is free of charge and delivered through GP practices but also through Health Board Medical Officers in schools and in 'black-spot' areas.

Immunisation services provided by GPs are paid for by the Health Boards through the General Medical Services (Payment) Board. Theoretically, GPs who achieve a 95% vaccination uptake level are supposed to receive a financial bonus for each child on their panel who has reached his/her second birthday in the calculation period. This, however, doesn't always occur due to communication / documentation problems.

Information and education

Various means are being used to inform the public, particularly parents, about measles immunisation. A TV cartoon type infomercial, features and interviews involving authoritative medical figures on radio and in the press have been used.

However, the findings of the National Review of Immunisation Programmes (The Health Board Executive 2002b), made it clear that a more systematic, varied and targeted public information approach is needed.

Information leaflets have since been made available to parents. A major initiative in 2002 by the HeBE has been the production of a comprehensive information and discussion pack on MMR for use by health professionals and by parents.

The reported links between MMR vaccine, autism and inflammatory bowel disease (Crohn's Disease) in children have been of interest to the press, radio and TV and have been the subject of news stories, interviews and features involving researchers and parents of autistic children. A report of a study carried out by one Health Board in 2002 showed that parents felt insecure and confused by such media coverage and are then hesitant to have their children vaccinated.

Programme related projects/campaigns

Special projects relating to measles immunisation are implemented by the HeBE at the national level and by the Health Boards at the local level. Such projects include the production of information packs and public information campaigns. There is however limited evaluation of such projects, an area which is to be addressed by the new National Immunisation Steering Committee.

Vaccination documentation and data collection

The GPs and Health Boards are responsible for the documentation of vaccinations given. Neither vaccination certificates nor chip cards are routinely issued. An individual child health record booklet to help parents keep a record of their child's health history, including sections to be completed by a doctor or nurse e.g. on vaccinations given, is available but not in universal use.

Data on immunisation status, vaccine uptake and measles incidences are routinely reported to the National Disease Surveillance Centre by each Health Board and published in a quarterly report. At local level data is collected by the Health Boards through GPs and other medical staff. At present this data is sent electronically for entry into a separate central surveillance system. It is planned to transfer the data directly into a new single integrated system, however, at the moment, information about immunisation and vaccination can only be accessed in a number of separate Health Board databases, a process which requires time and effort.

The main data gathering method is linked to GP claims for payment which must provide data over a range of fields. Data is also provided by Health Board Medical Officers in respect of school or special clinics. Both of these data collection methods support continuous systematic reporting but some GP claims are sporadic and time lagged.

Programme monitoring and evaluation

The performance of measles immunisation programmes are assessed using criteria such as the percentage uptake rate and the incidences of measles. A number of marketing type criteria have been piloted to measure the impact of public information campaigns related to immunisation and will be developed further in line with the development of more systematic, targeted campaigns mentioned earlier.

The ERHA has one of the lowest measles vaccination uptake rates in the Republic of Ireland and as a consequence the highest measles incidence rate. The last measles outbreaks which have occurred in Ireland have been in this region. However, the low vaccination levels in the region reflect the situation in the whole country, (Eastern Health Board 2000). The new organi-sational and governance approach outlined in Fig.3 is aimed at improving this situation.

Disease surveillance

As soon as a medical practitioner becomes aware of or suspects that a person on whom he/she is in professional attendance is suffering from, or is the

carrier of an infectious disease, he/she is required to transmit a written notification to the relevant Medical Officer in his Health Board.

Under new regulations in 2000, the National Disease Surveillance Centre (NDSC) was assigned responsibility for the collation and analysis of weekly notifications of infectious diseases, taking over from the Department of Health and Children. Thus the NDSC is responsible for the national surveillance of vaccine uptake and incidence of measles disease, with the department of public health medicine in each Health Board being responsible at the next level.

Since 1999, the NDSC publishes quarterly reports showing uptake levels for all Health Board areas and this receives wide dissemination, including to the media, which from time to time carry reports on low uptake concerns. The NDSC may also issue a press release specifically relating to measles, e.g. linking incidence of the disease to low immunisation rates.

For the period 1997-2001, in measles immunisation and incidence data collected from the participating regions, it was not possible to differentiate between confirmed and just clinically diagnosed cases. Limited information on hospital admissions due to measles is available.

An enhanced surveillance system for measles commenced at the beginning of 2003 in the whole country which aims to correct the above points amongst others. It is hoped to have more detailed information on measles cases in the near future.

6.4 Breast cancer screening programmes

There are no defined programs of professional breast examination and it is usually carried out by a breast surgeon or specialist breast nurse in specialised breast clinics in some hospitals.

Breast self-examination is not promoted in Ireland as it was feared that it could either cause anxiety by omission (women who do not self-examine may feel guilty for not doing so) or by a lack of knowledge (women who think that they have found something may worry unnecessarily).

Mammography screening programmes are the only official breast cancer screening programmes being used in Ireland. The National Breast Screening Programme, known as BreastCheck, was established in 1998 following a pilot period from 1989 to 1994, with the aim of reducing mortality from breast cancer by 20% over a 10 year period. Phase 1 of the programme started in February 2000 with the screening of women between 50 and 64 years of age in the combined Eastern/Midland/North-Eastern region.

Organisation of programmes BreastCheck is jointly overseen by the Health Boards for the early diagnosis and primary treatment of breast cancer in women. A statutory joint board, the National Breast Screening Board, was established by the Minister for Health and Children whose members consist of the Chief Executive Officers of the Health Boards and other nominees drawn from the disciplines involved in the early diagnosis and treatment of breast cancer in women, and a consumer representative (The National Cancer Forum 2003).

This Board, under the direction of the Health Boards, is responsible for instituting, coordinating and carrying out the programme.

The BreastCheck programme is managed locally by Clinical Directors who are responsible for their unit and its team, they report to the Project Director. The programme also has its own IT system, epidemiologist, statistician and researcher.

Funding for the programme is provided from national taxation by the Minister of Health and Children to the ERHA and Health Boards in the combined regions covered by the current phase 1 of the programme and they are required to meet the expenses of the National Breast Screening Board in such proportions as they may agree, or, failing such agreement, as may be determined by the Minister.

The Breast Screening Programme is managed and organised centrally with decentralised multi-disciplinary clinical units for screening, recall and assessment which are adjacent to a host hospital for the provision of primary treatment.

Screening strategy

Women aged 50-64 years living in the combined regions covered by the current phase of the programme are personally invited in writing to attend for screening at either a static or mobile unit, at a specific time and date, which can be changed to suit their convenience. Women are given seven days of notice before their appointment.

The population database for the areas concerned is used as a source of personal details for the women resident there. The database is formed using data from the following sources: Voluntary Health Insurance, General Medical Services and Department of Social and Family Affairs; and self-registration is used to supplement the database.

Screening for the BreastCheck programme is done at two clinical units, each of which has two mobile units. The two centres were chosen on the basis of established expertise in breast cancer at both hospitals.

Two view mammography is carried out at every round and the European Quality Assurance Guidelines are followed very closely.

There are no charges demanded for individual mammography provided under the programme; targets are set for each quality parameter of performance such as percentages of attendance, recall, and cancer detection rate.

A plan for the roll out of phase 2 of the programme – expansion of the programme nation-wide – was submitted to the Department of Health and Children in 2002.

Dissemination of results

Mammography is carried out by radiographers and the mammograms are read by two radiologists. Following mammographic screening, a woman is either informed that her mammogram is normal and that she will be recalled in two years (provided she remains within the specified age range of 50-64 years at that time) or is recalled for further assessment if an abnormality is detected. BreastCheck runs assessment sessions once or twice a week. The programme aims to send out results within three weeks of the mammogram and to ensure that women are offered an appointment for an assessment clinic within two weeks of being notified of an abnormal result. At the assessment clinic, the women are seen by a consultant doctor and supported by Breast Care Nurses. Assessment results are sent within a week and women are kept informed of any delays regarding results.

Women diagnosed as having cancer are fully informed about the treatment available to them and have the right to refuse treatment, obtain a second opinion or choose alternative treatment without prejudice to their beliefs or chosen treatment. There are special Breast Care Nurses to support the women before and during treatment.

Information and education

There is a lot of media interest in the success and usefulness of mammography screening and also in the extension of the current phase 1 of the programme to a fully national programme.

A Women's Charter was established within the BreastCheck Programme to inform and encourage women to give their views about the programme and any other related points of importance to them (BreastCheck 2002).

Health professionals involved in the programme are regularly informed about current recommendation and new developments via relevant jour-

nals, articles and press cuttings which are circulated. Monthly staff meetings are also held and radiographers have joint meetings 3 times a year.

Programme related projects/campaigns

At present the only campaigns held in relation to the breast cancer screening programme are media campaigns. Success of such campaigns is assessed by the attendance rates, which for BreastCheck are over 70% to date.

Programme monitoring/evaluation

Data on different aspects of the programme such as numbers of women invited, attendance rate, referrals for further assessment and cancer detection rates are collected by BreastCheck in its centralised database.

Rigorous audit and quality assurance is an integral part of the screening programme to ensure that women invited for screening receive the best quality of service.

The performance of the programme is compared with predetermined standards based on the third edition of the European Guidelines for Quality Assurance in Mammography Screening.

In 2001, a team of experts in radiography, radiology, pathology, surgery, physics and epidemiology validated BreastCheck's guidelines for quality assurance in mammography screening. This was done in agreement with the European Centre for Quality Assurance in Breast Cancer Screening (EUREF). Recommendations from this evaluation and the input from the European Manual on Quality Assurance provide assurance that the quality parameters reached by the Irish National Breast Cancer Screening Programme are to internationally approved standards (BreastCheck 2002).

Disease surveillance

BreastCheck has centralised data on all cancers detected. There is also a National Cancer Registry in Ireland where all cancer cases are documented by so called 'Tumour Registration Officers' (TRO). These are qualified nurses who undergo specialised training in cancer registration. The National Cancer Registry (NCR) has eighteen such officers and between them they cover all the hospitals, hospices, nursing homes etc. in the Republic of Ireland where the data is actively collected.

Confirmation of exact recording of tumours is facilitated by assistance from pathologists and clinicians to whom the TRO will go to if extra verifica-

tion is required. The data is recorded onto a laptop computer on site and is transferred electronically to the NCR headquarters for quality control. Once quality control is complete, an annual report is produced on the incidence of cancer in Ireland.

The NCR analyses national data whilst BreastCheck analyses its own data.

7) Veneto – Italy

7.1 Demography

Veneto is one of 20 regions in Italy, and each of them is governed by an executive and a regional council, both democratically elected. 4.5 million of the country's 57.7 million inhabitants live in the region of Veneto, an area of 18,364 km^2.

Of the female population 0.56 million are in the 50-69 year old age-group targeted for mammography screening.

7.2 Organisation and structure of the health care system

Italy's health care system is a regionally based national health service that, like the UK, provides universal coverage free of charge at the point of service. The system is organised at three levels: national, regional and local. The national level is responsible for ensuring the general objectives and fundamental principles of the national health care system whilst the regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefit package through a network of population-based health management organisations (local health units) and public and private accredited hospitals.

The Ministry of Health, the main central institution responsible for health, manages the National Health Fund and distributes resources to the regions. Its role in financing is restricted to allocating the resources from the global national budget and ensuring uniform availability of resources in the regions. The regions finance the remaining health care expenditure from their own sources.

In accordance with the decentralisation process occurring in Italy's National Health Service since 1992, regional governments, through their regional health departments, are responsible for legislative and administrative functions, for planning health care activities, for organising supply in relation to population needs and for monitoring the quality, appropriateness and effi-

ciency of the services provided (European Observatory on Health Care Systems 2001b).

Regions are also responsible for determining the size and organisation of local health units and monitoring their operation. Local health units are geographically based organisations responsible for assessing needs and providing comprehensive care to a defined population. Veneto has 21 local health units.

7.3 Measles immunisation programmes

The measles vaccine was introduced in 1979 in Italy as a single vaccine which was replaced by a single dose MMR vaccine in 1982 (European Sero-Epidemiology Network ESEN 1998).

Organisation of measles immunisation programmes

The Ministry of Health compiles the national immunisation regulations and policies together with the Inter-Regional Infectious Diseases and Immunisation Committee. It also evaluates obligatory notification of diseases preventable by vaccination. The Health Prevention Department is responsible for disease surveillance at the national level.

There is a national plan which determines the vaccines which are to be given by statutory law (obligatory on the part of the provider) and recommended ones. The planning, organisation and implementation of programmes is the responsibility of the regions, which work together towards the elimination of measles. The regional governments determine the immunisation programmes, which are then organised and managed by the regional public health service and the local health units.

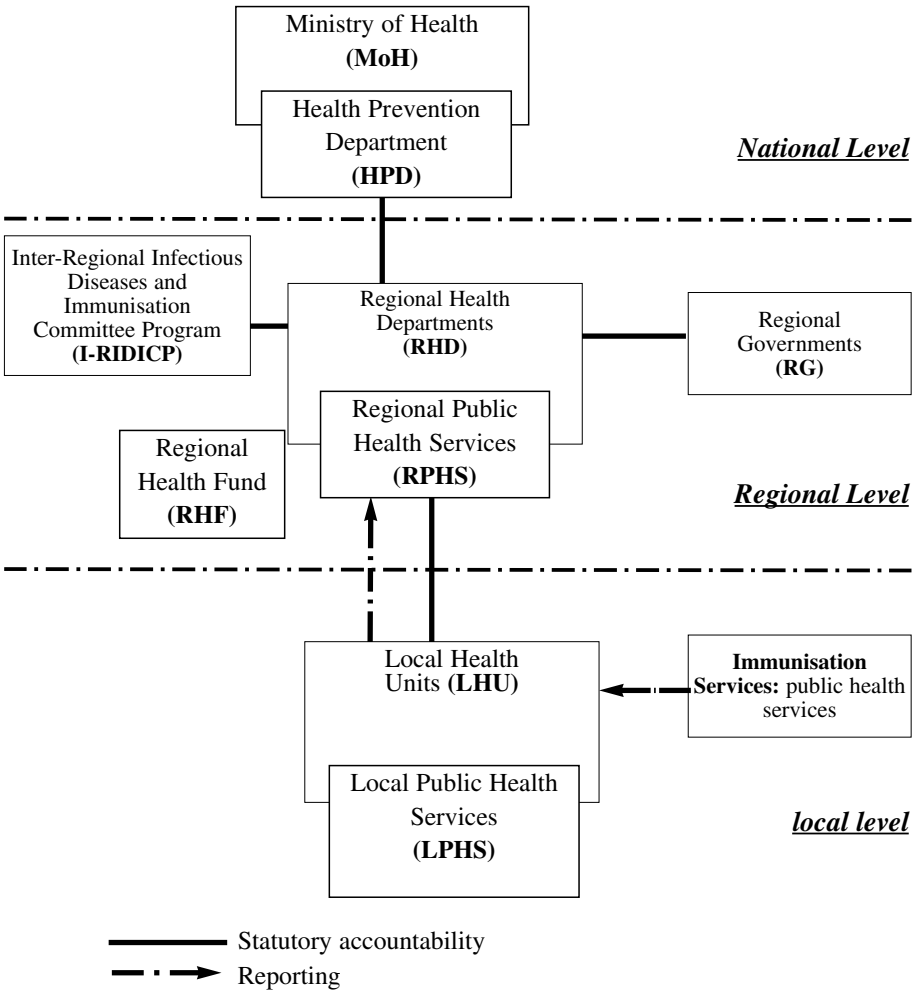
The regional programme is implemented by the epidemiological and public health services of the Health Prevention Department and by the public health services of the Health Prevention Department at the local level (local health units). These organisations also coordinate the programmes at their respective levels.

The regions instigated an Inter-regional Infectious Diseases and Immunisation Committee, which together with the Ministry of Health and the National Health Institute formulate targets for the immunisation programmes. The targets are in line with those set by the WHO for the European region, e.g. 95% vaccination uptake rate.

A measles immunisation programme which includes programme guidelines is currently being established by the regions together.

The organisations involved in the realisation of measles immunisation programmes as well as the levels at which they operate are illustrated in the organigraph below (Figure 4).

Figure 4. Organisation plan for the measles immunisation programme in Veneto Region, Italy



Vaccination strategy

In the Veneto region, MMR is given as a single dose to children at the age of 12-15 months. All children are invited to be vaccinated and a recall system is used for those who do not turn up.

The public health services of the local health units are responsible for the written invitations and they also maintain vaccination registers.

Vaccines are procured by the local health units, who distribute them to the immunisation services - public health practitioners, paediatricians and health workers - in their areas. Vaccination is only carried out with informed parental consent; however written consent is not required.

Information and education

Parents, and the public at large, are informed about the immunisation programme via campaigns in the forms of posters, pamphlets available in the local health units, and information forms given to parents during the vaccination notifications. The general public opinion is not measured.

Vaccination services personnel are informed about changes or new information regarding measles and/or immunisation through circular letters containing recommendations and immunisation campaign results.

Currently there are no structured programmes involving the media dealing with measles immunisation.

Programme related projects/campaigns

Following the measles outbreak which occurred in the Veneto region in 1997, the region enforced a measles immunisation programme for a period of 4 years (1998 - 2001). The programme entailed cohort catch up vaccinations for the groups with low vaccination coverage. During the campaign, more than 150,000 infants and approximately 69,000 individuals between 2 and 21 years of age were vaccinated, the latter comprising the ‘catch-up’ group. The programme was evaluated through data collection of the vaccine coverage in the cohorts involved in the programme. The regional annual incidence rate went down dramatically in 1998 and the following three years of the campaign.

Vaccination documentation/data collection

The public health services of the local health units maintain vaccination registers and are responsible for the overall documentation of immunisation details. They collect immunisation and disease data at the local level whilst the regional Epidemiological and public health services do so at the regional level and The Health Prevention Department of the Ministry of Health at national level.

Immunisation status is checked biannually and at school entry.

Programme monitoring and evaluation

All regions have to supply data relative to the number of vaccine doses administered each year and the vaccine coverage at 24 months of age for MMR and other vaccines to the Ministry of Health. The Ministry of Health uses these figures to evaluate the programme. It also evaluates the obligatory notification of diseases preventable by vaccines.

Disease surveillance

Measles surveillance is maintained on a national level with data transferred through the health service levels to the Department of Health prevention in the Ministry of health. The measles data collected by GPs or paediatricians is transferred to the public health services of the local health units where it is stored in a regional software programme before being forwarded on a monthly basis to the regional Epidemiological and Public Health Service who in turn forwards the data to the Ministry of Health.

The regional Epidemiological and Public Health Service analyses all data collected in the region and prepares annual reports which are then sent to the services of the local health units for distribution to the immunisation services providers and to paediatricians.

7.4 Breast cancer screening programmes

Mammography screening is the methodology being used for breast cancer screening in the Veneto region. Although professional breast examination is offered within a normal clinical work context, e.g. during GP or gynaecological consultations, no programmes for professional breast examination exist and no data is collected.

Breast self-examination is at times promoted within health education activities, but again without any clearly defined programme. In some mammo-

graphy screening programmes, after a negative mammogram, women are advised to regularly perform breast self-examination, but no practical training is given.

Organisation of programmes

The Veneto mammography screening programme started inviting women in 1999 in 10 of the region's 21 local health units. In 2000, the programme was initiated in two more local health units. Meanwhile, 17 units are implementing the programme.

The public health departments of the local health units together with radiology, surgery, oncology and radiotherapy departments are responsible for the planning of the mammography screening programmes in the region. The coordination of the programmes is normally done by the Public Health Department, however, a few are coordinated by the Radiology Department.

Radiology departments are mainly responsible for the implementation of the programmes, which are run according to guidelines issued by the National Oncology Commission which are in turn based on the European Guidelines. Screening programmes are part of the „LEA" (essential health services) and as such are financed entirely by the government within normal budget. Nevertheless, to promote the implementation the Regional Government and the Ministry of Health have repeatedly granted additional funds.

Screening strategy

The primary aims as stated in the regional program reports include the early diagnosis and treatment of breast cancer and the associated mortality reduction, whilst the secondary aims concern the use of conservative and, as far as the women concerned, acceptable therapy.

All women between 50 and 69 years of age who are registered as resident in the 17 local health units, where the programme has been implemented, are personally invited (with appointment) every two years for a two-view mammography examination. Self-registration is also used to supplement the registers and services provided free of charge to all women who attend.

A special information system is being developed for the screening programme. The computerised system will not only be used for invitation purposes but also for the storage and retrieval of programme data.

The regional targets set for the screening programme include, expanding the programme to all 21 units, a participation rate by targeted women of at least 70% and that screening is available biannually.

Dissemination of results

Results are disseminated differently in each region, in 8 local health units, a so-called 'standard organisation model' is in operation. First, all the mammograms are read, and then participating women are recalled for further assessment. Three local health units use a system where the reading of the mammograms and the conduction of non-invasive further examinations are done in one sitting. In the units where the standard organisation model is followed, an average of 88% of negative results were sent out within 21 days from the day of examination. In case of a positive or unclear result, the woman concerned is invited by telephone to an assessment session. 73% of the further assessments were achieved within 21 days of the initial examination.

Information and education

There is a lot of interest in the mammography screening in the media as well as within the population, with a generally positive opinion reported from women and the general public. Posters and meetings with population groups are used as means of disseminating information about the programme. Invited women also receive information leaflets and are given a free telephone number where they can get more information or raise questions.

Professional training meetings are organised once or twice a year for those involved in the realisation of the programmes.

Programme related project/campaigns

Apart from the information sessions with population groups, there are currently no projects or campaigns being held in relation to mammography screening programmes. However, there are plans for implementing campaigns in the future.

Programme monitoring/evaluation

Data on different aspects of the programmes such as number of women invited, participation rate, referrals for further assessment and cancer detection rates are collected by the local health units. The coordinating department of each local health unit uses these figures to monitor and evaluate their

respective programmes. A common and specific information system is adopted by each unit and the data collected is forwarded to the Regional Reference Centre for Monitoring and Evaluation on a yearly basis.

Disease surveillance

Personnel at the regional cancer registry in the Veneto region are responsible for the documentation of cases in the cancer registry. Data are provided from the local health units, analysed, and published on an annual basis.

EXERCISE: Comparative Research on Regional Health Systems in Europe

Task: Students will work individually in the first phase of reading the introductory material (8 regional reports), while in the second phase they will discuss their findings in small groups (3 to 5 students). Third phase will be plenary presentations of small-group work. The whole exercise requests 4 hours, because students are obliged to deliver written reports.

Instructions for students:

1) Choose the best measles vaccination programme and the best breast cancer screening programme and present your arguments.

2) Think of other services suitable for benchmarking.

3) Collect the appropriate information on measles vaccination and breast cancer screening from your own region of origin.

4) Using the example of your own region, what is your judgement with regard to the significance of the 2 selected programmes as indicators for the quality of health care in your region in general?

5) Think of how benchmarking would look like using health indicators (5).

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HEALTH SYSTEMS MANAGEMENT

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Health Management: Theory and Practice**
Module: 2.1	**ECTS (suggested): 0.75**
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Keywords	Health services management, planning, organizing, staffing, leadership, controlling, evidence based
Learning objectives	After completing this module students and public health professionals should have: • increased their understanding of management theory and practice, and development of interest for health services management, • explored the current ideas and trends in health services management, as well as basic characteristics of managing health services organization, • identified key interrelated components in health services management (planning, organizing, staffing, leadership and controlling), • improved their skills in management and raised their understanding of modern evidence based management, • explained and justified their intentions for seeking a higher standard of management at their own place of work.
Abstract	Modern management is a process of creating and maintaining an environment in which people working together may accomplish predetermined objectives. It occurs in a formal organizational setting through utilization of human and other resources by which demands for health and medical care are fulfilled by provision of specific services to individual consumers, organizations and communities. Management, as a universal and complex process, open towards its environment, consists of five essential components: planning, organizing, staffing, leadership and controlling. The activities of an effective manager imply basic skills providing the balance among these interrelated components and skills in evidence based management.
Teaching methods	Teaching methods include lectures, students' individual work under the supervision of teacher and interactive methods such as small group discussion. Before introductory lecture the small exercise could be organised as brainstorming („What does management mean to us?"), in order to increase students' motivation for learning and interest in the content of the module. After the introductory lecture students will work individually by writing down the framework for their own professional development. This work will followed by the lecture and exercises focused on the health services management. Students would have opportunities to discuss in small groups different case problems and to present possible solutions. As an example of, the case problem is presented in this module. They would also have opportunity to search through the Internet under the supervision of teacher in order to explore some of the famous electronic libraries and to select examples of good managerial practice based on evidence. These will serve as base for individual work which is supposed to have a written case problem of national health service as output.

Specific recommendations for teacher	It is recommended that the module should be organized within 0.75 ECTS credit, out of which one quarter of ECTS credit will be done under supervision, while the rest is individual student's work. It is supposed the 1 ECTS is equal to 30 hours. Teacher should advise students to use as much as possible electronic management libraries during individual work to gather ideas how to write and present their own case problems.
Assessment of Students	Multiple choise questionnaire and case problems presentations.

HEALTH MANAGEMENT: THEORY AND PRACTICE

Vesna Bjegović

Management in health care system is an area of scientific management to which an ever-increasing attention has been paid under conditions of economic and socio-political changes. Nowadays, the importance of an effective and competent manager is emphasized in solving problems referring to functioning of health organizations and related services in changing environment.

Development of management theory

Organizing of people for achieving common goals and utilizing management principles have been a phenomenon known for centuries, its development and changes running parallel with human society. However, not before the very close of the XIXth century did the first scientific theories on management appear when there imposed itself, as a goal of economic and non-economic companies, the basic economic principle: achieving maximal results with minimal investment (1). In that period, Frederick W.Taylor (1856-1915) may be viewed as an author of 'scientific management'. In his research in the field of work organization, he recognized the importance of achieving cooperation and harmony in teamwork, as well as workers' improvement in accomplishing better job results. His capital work 'Principles of Scientific Management' expanded the management utilization. Nevertheless, many hold the view that greater merit for the real beginning of the science in question should be given to Henry Fayol (1841-1925) and his work 'General and Industrial Rights'. He pointed out general management principles: linkage between authority and responsibility, the unity of leadership and teamwork, all of which represent the basis of classical school of management even at present. Also, studies of other scientists in the same period, such as Frank B.Gilberth (1868-1924), Lillian M.Gilberth (1878-1924), Max Weber (1864-1920), contributed to further management theory development. The famous Hawthorne experiment carried out with workers of the Western Electrical Company powerplant in Chicago from 1927 till 1932, as well as the findings of the researcher named Elton Mayo (1880-1949) threw a new light on classical theories. The study was begun as research into the impact of

illumination on work productivity of experimental group of workers. Regardless of the illumination level being increased or decreased, the productivity kept rising. Furthermore, there were experiments with modifying resting periods, working hours' reduction and wage changes. None of these could have explained the alterations in work productivity of the experimental group. The researchers ascribed the productivity modifications to social attitudes and relationships in the working group. Namely, the group started regarding itself as 'noticeable', gaining the feeling of being important. This experiment outlined the significance of work motivation and initiated a series of psychological theories of management. After 1950, behavioral sciences showed great interest in studying motivation as an important means for achieving predetermined goals. The authors of motivation theories, still applied in management practice, are: Abracham Maslow, Frederick Herzberg and Douglas McGregor. Studying individual and collective behavior at place of work, they noticed that management was not only a technical process and stressed the importance of a positive attitude towards people being managed. Due to an extraordinary concern for management over the recent years there have been encountered the most diverse approaches to studying and analyzing its theory and practice. There have been numerous operational approaches analyzing management as a complex and open system in a dynamic balance with the environment (economic, technological, sociological, political, legal, ethical and cultural) (2,3).

Development of interest for health services management

It may be noticed that only within the last three decades has the management become an area of significant interest in health systems, too. Until that time, the management was regarded as a scientific discipline suitable only for big corporations and commercial companies, and not for social domain like health care (4). This is understandable bearing in mind that health services organizations used to be less complex, with significantly lower costs and underdeveloped technology. At the beginning of the XXth century, managerial roles were assumed by a physician-administrator, appointed by the Managerial Board with an exclusively autocratic managing style and one-dimensional distribution of authority and responsibility. Only two professional groups were in charge of providing health care services, namely a physician and a nurse. Still, with making health services organizations more complex, increasing gaps between medical technologies advanced and limited resources as well as by environmental changes, objectives of health services organizations have been changed and made complex in relation to the society as a whole. The situation

in terms of showing concern for management has also changed and presently there is an ongoing affirmation of the managerial skills application in health services organizations, too.

The essential characteristics of external environment in which today's management of health services organizations is taking place include population aging, miraculous but costly diagnostic and treatment technologies, efforts to modify life styles and underscore health promotion and prevention (5). Also, modern health systems in numerous countries are faced with ethical and economic crisis of unpredictable level. Political, social and, most frequently, professional groups are trying to solve the crisis by introducing various changes in health legislation and functioning of health services organizations. In view of the alterations mentioned, Peter Drucker, a distinguished management theoretician, has noticed a paradox in health services organizations in which there is a growing work pressure on employees, but at the expense of additional activities being minimally or completely unrelated to those jobs for which the employees were qualified (6). An illustrative example makes an increasing number of nurses in hospitals, while there have been a decreasing number of hospitalized patients. A paradoxical situation occurs: nurses spend only half of their working hours doing jobs for which they are qualified and paid for. The other half of the time spent at work they devote to activities for which neither their nursing degree nor skills are required, that is filling in various blank documents and forms. Likewise, in the last decade of the XXth century, there was a growing recognition of a conflict between doctors (as leading professional group in a health services organization privileged to do autonomous clinical work) on one hand, and managers (whose job includes controlling the work of employees), on the other. In accomplishing effectiveness, managers traditionally analyze resources, while doctors review clinical activities and patients' outcomes. In this way, a potential conflict is stressed in which a lot of energy is needlessly wasted in many health services organizations. Such environment makes a challenge for successful managers, with the practice of effective leadership becoming one of rare solutions for the survival and development of health services organizations (7,8).

The majority of health systems in Central and Eastern Europe are undergoing the process of transition from bureaucratic, centralized to much more efficient systems with decentralized responsibilities, private sector introduction as well as more effective trends towards a higher level of health care quality (9). In these countries, there has been a significantly growing interest in professional management of health services organizations and continuing education in the field.

Characteristics of managing health services organizations

Basic concepts, principles and skills in management encountered in industrial and other organizations may also be applied in health care institutions by respecting their social roles. Seven principal roles of health care service are distinguished in each society:

- It represents a part of national state policy;
- it employs a large number of people;
- it provides health care;
- it does different kinds of research;
- it educates on a continuing basis;
- it represents significant economical factor; and
- it plays an important role as a country's social stability factor, taking into account people's expectations and trust put in this service.

The specificities of managing health services organizations are determined by the vital roles outlined above.

Health services organizations nowadays are known, in the management theory, to be the most complex organizations with the most complex management, a modern hospital being top ranking by its complexity. Extensive working activities' differentiation and specialization are obvious, and working tasks are accomplished by a number of different participants in terms of educational level, training and functions. Contrary to a typical business organization, the authority structure in managing a health services organization is divided among three authority and responsibility centres: Managerial Board, Doctors and Administration (4).

Managerial Board is legally responsible for the organization as a whole, including provision of health care, public relations and assistance in resources supply for its functioning. If an aspect of basic social roles of a health service is viewed, it is the Managerial Board that most commonly reflects a profile of the community comprising a health services organization. It means that the former consists of delegates from various social groups of certain educational level and experience.

Doctors, comprising a medical board, but others as well, have a powerful role in management, since they are held responsible for the majority of cost rendering decisions made. As a predominant profession, doctors in health services organizations participate, at least, in three management

processes: managing a patient, managing a doctors' team and managing a health services organization. This makes them 'the potentially best managers in health services organizations' (10). Related to this centre of management structure, many underline a typical phenomenon of health services organizations: for doctors, having power and authority does not imply being also responsible for financial risks. In spite of being highly educated in the medical area, most doctors are very little acquainted with their real working environment, since they spend most of their working hours with patients or are devoted to their own advanced training. Thus, there occurs a phenomenon of separation between clinical autonomy (freedom and opportunity for doctors to work in the best possible way to help their patients) on one hand, and institutional interests, on the other. Due to increasing costs of health care service provision, doctors are no longer in a position to make independent clinical decisions and provide patients with all the services they find beneficial for them. For this reason, it is impossible to enable effective management of health services organizations without a considerable doctors' participation in decision-making concerning leadership.

Administration, composed of director, heads of departments and chiefs of assisting services, is the third and last authority centre in managing health services organizations, responsible for operational management, but with both limited scope of authority and knowledge about the process of working directly with patients. The task of the director of the institution is to plan, make decisions, coordinate and control activities of the employees in order to ensure efficient and effective work with patients. In numerous health services organizations doctors used to hold the position of directors (operational managers). However, in the course of time they kept being replaced, in highly developed countries, by professional managers who were not doctors (9). Such practice was not the same in some developing countries as well as countries of the Eastern Europe till 1990s. The managers role has always been attractive, but most frequently without either any improvement in the field of management or knowledge about managerial skills.

In the study of managing health services organizations, unlike other business companies, apart from the triple power and authority distribution outlined, there exist its *specific* responsibilities that must also be taken into account (11):

- responsibility *for the patient*, above all, within the scope of modern medicine and health promotion movement, with provision of the best possible health care, with minimal costs;

- responsibility *for the employed health workers* by recognizing their sensible requirements for safety in terms of wages, appropriate working conditions, promotions, but also identifying their fears caused by uncertainty due to positive effects at work (outcomes concerning the treated patients' health);
- responsibility *for a financier* and different social groups (donors, sponsors) supplying resources for functioning of the institution;
- responsibility *for the community (public)* in determining means for meeting the population health care needs; and
- responsibility *for oneself* by making efforts to perfect one's knowledge and skills related to management as well as readiness to make effective responses under conditions of continuing environmental changes.

Definition and key management components

There are many definitions of management and the following is very often cited: „Management is the process, composed of interrelated social and technical functions and activities (including roles), occurring in a formal organizational setting for the purpose of accomplishing predetermined objectives through utilization of human and other resources" (12). Management, as a universal and complex process, open towards its environment, consists of five essential components: planning, organizing, staffing, leadership and controlling.

Planning in management

Planning in management basically includes decision-making related to prospective services activities and objectives as well as how they may be accomplished. Decision-making implies the following: problem definition, information gathering, alternative solution making, the best option choice, policy planning, policy undertaking and evaluation of the results obtained. The most varied methods, more or less effective, facilitate decision-making, and thay are one of the basic topics in modern schools and courses for managers, such as: intuitive methods; simulation methods, models and role-plays; decision tree; PERT; linear programming and others (5).

Success in all other managerial roles depends on planning, since it also

implies a selection of the single solution among different alternative ones offered. Efficient managers spend a lot of their working hours, perhaps even up to 40%, developing and improving the company's work schedules, formulating them in such a manner that both the organization's short-term management is successful and, at the same time, its long-term business activities more effective. Beside classical classification of plans according to planning time perspective, Cohen's division is also very useful for managerial staff, and is the following (13):

Corporate plans cover the company as a whole most frequently for the period of 5 to 25 years.

Strategic plans refer to changes introduction, most often in specific organizational areas, for the period of 2 to 5 years.

Leadership plans represent implementation of steps outlined for strategic plans and are related to improving the organization's activities, correcting weak points and possible flaws, allocating current resources for accomplishing the predetermined objective and adjusting to the existing environmental changes. These are usually annual plans.

Operational plans are associated with shorter-term steps outlined for leadership plans as well as common activities of certain organizational sections.

Financial plans determine financial resources and equipment required for accomplishment of goals, most frequently for a year.

Within planning, the vital issue in modern management theory and practice comprises the development of goals in the form of plans expressing the type of final results of organizational activities (4). Sound management is considered to imply an ability to point out goals and rank them according to their priority, as well as the ability to utilize proper means to maximize those objectives. Although there is a tendency to express the goals in quantitative manner, it is this 'virtue of vagueness' that is significant in determining general objectives and the necessity for their continuous reconsideration. Both managers and employees should take part in establishing objectives, and numerous studies have shown that such approach leads to increased working performance since it is clear to the individual what is expected of him/her to do. Also, people are ready to work on more demanding goals if they have participated in their development. Therefore, one of the management types frequently applied in health care is 'Management by objectives' whose concept

was introduced by Peter Drucker as early as in the middle of the XXth century. 'Management by objectives' is a process in which both superiors and subordinates collectively identify general objectives defining, for each individual, a scope of responsibilities for fulfilling the expected results, as well as criteria upon which individual contribution to working process is monitored and assessed. The goals may have a great impact on the employees' participation in managing a health services organization. Provided that the course of action directed towards economic acquisition is imposed upon by the objectives, the doctors' activities may be restricted by the necessity for cost containment and profit enlargement. On the other hand, if the objectives favor competence and public health orientation, a greater participation of doctors in management may be expected.

Organizing in management

After the designing of plans, the next management component - organizing, becomes significant. Organizing implies interaction of all organizational resources (manpower, capital, equipment) in order to accomplish the goals most efficiently. Organizing, thus, includes resources organization: individual or group task assignment and responsibility shift to individuals for achieving group goals. Good organizational development and maintenance have been considered as crucial factor of successful companies with organizations representing social subsystems mobilizing people, power and resources in terms of attaining determined, collective social objectives. This is achieved through appropriate organizational structure. Structure, according to management theory, represents establishment of patterns of either interrelated organizational unit components or management components (14). After the work division, it is necessary to group works and individuals who will perform those works, through the establishment of adequate organizational units, such as sectors, services, departments, etc. This process is usually termed departmentation (sometimes called departmentalization), which recognizes relationship between dividing work and the need to then coordinate divided work to achieve satisfactory results. Bases for departmentation have increased, but the basic concept is largely unchanged. Mintzberg suggest six bases for grouping workers into units and units into larger units (5,15):

- knowledge and skills (hospitals group surgeons in one department, pediatricians in another),
- work process and function (for example: department of finance in health services organization),

- time (hospitals and other health services organizations are 24 hour-a-day operations; some workers are grouped into day, evening, and night shifts),
- output (many health services organizations group workers by whether they produce inpatient or outpatient services),
- client (workers are grouped by patients / consumers served; for example geriatric or women's health programmes), and
- place (workers are grouped by physical location, ambulatory health services downtown or in suburban locations).

Each organizational unit performs a part of the overall company's task. In the realization of its duties, it is connected to other organizational units. After determing the organizational units, managers for each of the units are also selected, and they are given authority and responsibility to direct the work of these organizational units.

Organization may be formal or informal. The first is characterized by firmly formulated policy clearly expressing what each employee's task is, as well as field of action in which an individual may work freely and creatively. The second, aimed at enabling successful company's functioning, has to be based on excellent interpersonal contacts. Organizations may also be divided into simple and complex. Simple organizations have one manager and several employees. They are usually informal, flexible, with supreme structure authority. As opposed to them, complex organizations consist of big hospital institutions compared to labyrinths. They are usually of a hierarchical, bureaucratic organizational structure with the stress on planning and rigorous control (4).

Forming the organizational structure can be achieved in different ways. The most acknowledged and used ways of forming organizational structure are: as per functions, products, territory, the project, matrix, and others. Functional organizational structure designs grouping activities, and defining the organizational units according to certain functions, which comprise an array of uniform and interconnected activities, by which a certain task or a part of the company's business process is realized in the best way. The essential advantage of a functional organization is that the staff is grouped according to specialties and is always at disposal. However, functional structure is characterized by inflexible hierarchical nature, autocratic style of leadership, rigidity and one-way superior-subordinate-directed communica-

tions. Product organizational structure devises an organizational unit to be formed for each kind of product. The advantage of such structure is that it can direct all resources and all activities onto a single product. The basic disadvantage of the product organizational structure is that it doubles the organizational units and cadre, which is unacceptable to smaller companies. Territorial organizational structure implies that organizational units are formed according to geographical regions they supply. This manner of forming the organization is rather convenient for big companies, widely extending their business on national or international level. In such an organization it is necessary to have a decentralized management, which requires additional control by the company's head management. Problems may also arise with transportation costs and due to the need for large number of personnel as manager for each particular region. Project organizational structure implies creation of a special organizational unit, a project team whose task is to realize the particular project. The advantage of such an organizational structure is its direct orientation to the realization of the task, an the fact that it enables more efficient realization, while the drawback of the project is mainly connected to duplication of the human resources, and problems with personnel after the project team is dismissed. Matrix structure is designed to ensure modern people-oriented management, it is flexible, with two-way superior-employee communications and good coordination among different units. It is a combination of the functional and project organizations. The idea is to benefit from the advantages, and diminish some disadvantages of the project and functional organizations. The advantage of the matrix organization is that it enables efficient management of a great number of projects and efficient utilization of resources, and it also alleviates conflicts between managers. Disadvantages are connected to more complex communication and reporting, as well as to potential instigation of conflicts in relation to resources allocation.

The most varied organizational forms may be encountered in health services organizations ranging from bureaucratic structure with clear-cut hierarchy, to matrix structure in which power of decision making is closer to those working with patients. Each organizational form has to be made in such a manner so as to be capable of functioning, enable each member to make his/her own contribution, and assist people to effectively accomplish common goals even under altered circumstances. This means that a good organizational structure is never static. Nevertheless, a bureaucratic structure is considered to be capable of functioning well in routine tasks. For organizations whose main purpose is research, different adaptive models make a far more adequate solution. An example of such model is a project structure ensuring swift switches of employees from one to the other project work phase with holding

flexibility in certain areas (such as research autonomy) and having rigorous control in others (e.g. financial resources).

Within organizing, *coordination* is an important activity related to providing conditions under which all the activities, inside the company, are realized through simple steps. In the early phase of management, this was considered to be the most important element. Nowadays, this is regarded as good for unplanned activities, or the periods known as 'management crises'. As organizations grew bigger, and planning much more important, the need for coordination kept decreasing. Presently, it is normal that with the plans falling through, the need for coordination is increasing.

Typically, managers make three simple errors in organizing, as a management component:

1) Managers do not leave enough freedom for decision making to their subordinates.
2) Too few subordinates are held responsible to a single manager. Interestingly enough, managers prefer organizing too few to too many workers, which results in unnecessary double cost expenditure for leadership jobs and forming of bureaucratic apparatus in the company.
3) Managers, in organizing, generally do not apply motivating methods: employee remuneration by work successfully performed and/or penalty in case of unsatisfactory work performance.

Staffing in management

Staffing is the third vital component exclusively related, as opposed to the previous two, to human resources planning. This role may be particularly conflicting for managers, since they are individually well aware of the staff significance for the company's successful operation, but also of a simultaneous restriction of methods available for effective staff policy implementation.

Staffing has its technical and social aspects (13). Technical aspects refer to human resources planning, job analysis, candidate recruitment for vacancies, their testing, selection, then performance appraisal, compensation and benefits, as well as employee assistance. *Social aspects*, directly associated with the impact on employee behavior and striving at work, are related to training and development, promotions, counseling and discipline.

The basic problems of staffing are the following: role defining of the newly employed, candidate working ability assessment and his/her

simultaneous getting acquainted with job tasks, evaluation of the success rate of the job done, and, finally, criteria establishment. In any job dependent upon staff quality and competence, staffing has to achieve high standards. Thus, for example, it is upon a manager to ensure that vacancies are filled with people who are:

- capable of fulfilling their intended role successfully;
- willing to make necessary decisions and perform an assigned task;
- planning to remain at their place of work for a reasonably long period of time; and
- getting along well and cooperating with other employees at place of work.

A very frequently asked question relates to staff norms, which would serve as guidelines in planning and employing. Norms for a so-called 'ideal service' are non-existent and will probably remain so, at least in the foreseeable future, due to, above all, relatively frequent technological changes in medicine as well as gradual alterations in the kind and nature of health problems. „Political norms" exist and usually represent combined study results of proper practice and expert opinions at a given moment, or result from negotiations of those concerned (the role of practice guidelines in the total quality management approach). In local circumstances, they may be of little use since they do not cover patient structure, assisting staff existence, department location and related factors. There are also so-called „if-then" norms based on somewhat more objective staff needs assessment, relying on the workload studies. Namely, if it is necessary to provide **x** services, and an employee may make a daily provision for **y** services, *then* **z** staff members should be engaged.

Common mistakes in staffing are the following: lack of human resources planning, inadequate monitoring and insufficient staff training and promotion. It is important to stress that decision making related to organizational staffing, lying at the root of effective management, is often a neglected activity. Managers in health (and other fields, too) frequently spend much more time in making decisions on the introduction of a new apparatus (diagnostic and/or therapeutic) than on employees, their promotion, transfer to new working posts, or engaging new employees.

Leadership in management

Directing involves a process of influencing employees to do their best to achieve group goals by team work. A good manager accomplishes this role using different motivating methods simultaneously, knowing the true nature of communication as well as successful communication with different social structures. The importance of employees' motivation is unquestionable and over the recent years there has been a tendency to replace „directing" by „motivating" (5). However, a person with excellent motivation, interested in his/her job, still has a need to be directed in his/her activities, since many people, in certain circumstances, prefer clear „orders" to individual decision making. Nevertheless, styles of the most effective managers necessarily include perfection in employees' communicating and motivating skills (16,17).

A managerial style is a kind of behavior in which a leader influences other people's work. Most frequently mentioned basic managerial styles are the following (1):

- *autocratic* (with high managerial authority, commanding, not leaving space for interaction or participation of others in decision making),
- *democratic* (enabling permanent interactions between superiors and subordinates, employee participation in decision making and creativity) and
- *laissez-faire style* („let (people) do (as they please)" style, based on complete individual freedom in decision making and work).

A style a manager will utilize is considered to be dependent upon his/her situation, and is characterized by critical dimensions such as (14):

- *result significance* - if a working activity has to be performed quickly, perhaps due to accidents or under conditions of crisis, health manager should adopt autocratic style, another style being required for other circumstances;
- *job nature* - if the job is routine and requires temporary influence, a manager must be more autocratic than democratic in determining what, how and where it will be done, however, if the job is creative, flexible, with other departments being time independent from job completion, a manager should adopt a democratic style;

- *employee qualities* - their training, education, motivation and experience may determine adoption of a particular style; if employees are untrained and inexperienced, a manager must make most decisions and vice versa; there are even such employees who, due to their own value system or previous experience, are unwilling to be accountable for decision making;

- *personal managerial qualities* - some managers because of their personality nature, prior experience, values or cultural features, function better adopting one style or another.

None of the styles mentioned is appropriate in all situations, although, nowadays, different forms of democratic style are regarded as more appropriate and, long-term, more efficient than the authoritarian styles. If only clinical practice and doctors as team managers including nurses, technicians and others are looked upon, it may be noticed that they usually utilize the autocratic style since they are held individually responsible for treatment. Different forms of democratic style are common for heads of departments and chiefs of staff.

Kenneth Blanchard, a psychologist, holds the view that an effective manager has to assume various styles in his/her work with employees (18). Which style the manager will adopt, apart from the given situation, also depends upon a developmental level of an individual. He defines the developmental levels according to employees' work competence and sense of commitment:

- If persons are incompetent for the job, but hard-working and zealous, they should be *directed*: clearly told what they should do, how, where and when, and then carefully supervised.

- Persons competent for the job, but lacking motivation or self-confidence are better suited to a *supportive style*: they should be listened to, encouraged, involved in problem solving and decision making.

- For those who are neither competent enough for the job nor devoted, an *instructional style* is the most convenient, providing support and directing.

- In highly competent and zealous workers, *delegating* is the best style. Little support and directing are implied - just to keep abreast of their work.

Among many attributes of effective managers cited as important are the following: high standard of personal honesty, firmness, ability to identify crucial problems, serenity, vitality, persuasiveness, decisiveness, consistency, personal integrity, enthusiasm, showing understanding for subordinates' attitudes and suggestions, anticipatory abilities and so on. Although the majority of remarkable leaders possess most of the personality traits outlined, there is no evidence that each one of them is really required. However, vanity, arrogance and breaking one's own rules are the least favorable attributes of managers.

Controlling in management

Controlling is a subsystem important for all the management components. It is most commonly defined as measuring and correcting the company's efficiency so as to ensure both achievement of goals and realization of plans (5). The controlling process in management involves the following: establishing standards, measuring efficiency, and comparing results against the established standards, correcting irregularities and timely informing. Controlling has to cover services functioning; health services provision costs, revenues, employees' discipline and informing (health care information system). Although necessarily pervading the whole managing process, the scope of controlling must not be large, so that by using it a manager has no time to pay attention to human interactions, that is paying attention to each individual, as well as suggestion acceptance and understanding the employees' existing problems.

The most varied types of control have been mentioned in literature: visual, automatic, control of exceptions, motivation-assisted control, budget control, daily charts, Gant's maps, network analysis, computer use (5). In small organizations, personal control of all functions and all employees may be established. The higher is the organizational magnitude and complexity, the harder is the control. Today, a good informational system is considered to be the most powerful control means.

The importance of strategic control has been particularly emphasized at times of big economic crises and extraordinary circumstances. Since the controlling system provides a signal to a manager for failure correction, identification of explicit strategic control would prevent „falling through" of many long-term plans, which makes a typical problem of less developed countries. Some managers make mistakes believing that successful leadership means carrying out control by reviewing different routine reports. However,

the essence of control is correcting deviations from the predetermined objectives.

Modern managing health services organizations is increasingly turning its attention to quality control in health care provision, too (19). It has been noticed that some managers are frightened and avoid applying quality control within a regular controlling system, being under impression that possible quality lacks might lead to additional, unnecessary expenditures. However, it is both in managers' ethical and commercial interest to minimize errors and incidents leading to patients' complaints and poor public reputation.

Skills of modern managers in health services organizations

Modern health care outcomes are greatly determined by health professional activities in that management effects may instantly be analyzed, based on managerial abilities to act upon behavior of doctors, nurses and other health care workers to do their utmost in achieving the best possible outcomes for patients.

The efficiency of the management itself, beside theoretical knowledge and training, mainly depends upon the existing evidence on possibilities of acting upon health care workers' behavior. The starting point is making efforts for organizational development characterized by decentralization in decision making, professional linkages and cooperation, demanding objectives, acceptable and transparent standards, responsibility division and decreasing job failures (20). In such organization, evidence based management should be developed. Within the programmes for education and development, there must be those oriented towards evidence using skills on the part of managers themselves. A „complete manager" of evidence based health care should possess, apart from general managerial skills, evidence based decision making skills, as well. These skills comprise the following (21):

- reference and abstract application,
- the use of individually defined key words,
- individual use of computers for search,
- reference management database search, including, beside Cochrane base, the bases covering topics in the field of health care administrations, economy and planning (2,3,22).

Apart from the skills mentioned, requiring, in most cases, special education, managers of health services organizations should also possess skills

of research evidence implementation into everyday practice, as well as skills of managing alterations, projects and, finally, team work. Unfortunately, certain studies have shown that, when specific skills needed for evidence based management of health services organizations are taken into account, managers themselves inhibit the development of such approach.

In the past, managers of health services organizations were responsible for organization and system, but nowadays, with the shift towards evidence based health care, they have to balance among clinical, managerial and organizational performance (23). Having in mind numerous restrictions and the time required for the development of such approach, as well as suspicion among certain theoreticians concerning uncertainty of its possible implementation due to those restrictions, *evaluation informed management* has been recommended, as a transitional strategy (24).

Besides, an important recommendation for evidence based management is the one related to modifying existing educational programmes via multidisciplinary teams, so that clinicians may educate themselves from management area, and managers of health services organizations from clinical research.

EXERCISE: Managing Health Services Organizations

The purpose of the exercise is to provide students with basic information on managing health services organizations and their functions (components), and also to find out how managerial skills may be mastered by learning and training.

Task 1: Professional development (career) plan design

Students work individually, by writing down their own goals in professional development for a ten-year period, as well as conditions required for their accomplishment. Several students present their reports. A teacher, after that, points out planning as one of the important functions of management being especially aggravated under conditions of critical environment. Also, the term „management" is defined, and its other functions quoted, such as: organizing, staffing, directing and controlling. Time: 30 minutes.

Task 2: Case Problem: How is Group Work to be Maintained?

The teacher introduces the topic by outlining possibilities of managerial skills training and stresses „case problem" solving as one of the ways of its achievement. Then, the supplemented practical case is read. Students, in groups of 5-6, discuss solutions, and then each group presents its reports. The teacher, upon that, provides a summary with a suggested solution, unless the students have discussed all the possibilities. Time: 60 minutes.

CASE PROBLEM: „How will you maintain group work?"

Dr Branislava Petrović, a newly appointed chief of staff in GP outpatient department of a health care centre, is worried about starting her new job properly. Just after several weeks at work, she noticed that the majority complained of being overworked. When she seemed to notice that one nurse was too slow in answering the telephone, Dr Petrović gloomily asked: „Why's it taking you so long to answer the phone? That's a very important thing for our service and I think it should be answered after the second ring!" The nurse answered: „We've so much work to do; I simply can't jump after hearing a ring." As the others were also making similar remarks, that still did not convince Branislava that they were overworked. In fact, Branislava knew that the new health centre manager was seriously considering cutting down of staff in the outpatient department unless their working hours were truly totally spent.

Dr Petrović was particularly unhappy about the time wasted by many of her employees on coffee breaks. To quote her own words: „On Tuesday I came

back from a meeting at 9.30 and offices were almost empty. The employees went for a coffee break and didn't come back even after 45 minutes!" This made Branislava issue an order for both morning and afternoon coffee breaks to last no longer than 15 minutes; also, no more than two employees could have a coffee break at the same time. Employees remained at their places of work, but it seemed that it took even longer to carry out examinations, interventions and administrative work. Branislava noticed that several doctors and nurses spent quite a long time on making personal telephone calls, while the waiting rooms were full of patients.

In issuing her second order, Dr Petrović announced: „Personal telephone calls shall last 2 minutes at most and there are to be no more than two such calls daily. In addition, our work is too slow! We keep our patients waiting too long and prescribe too many drugs!" In spite of Dr Petrović's efforts, there were no improvements in the work performance of the outpatient department. Only one nurse (Marija) started showing quite unpleasant manners towards her chief of staff. After the latest order, Marija told Dr Petrović: „You're really trying hard to make an impression, maybe wishing to be promoted to the Assistant Manager. When you leave, we'll be left with all these new changes: restricted drug prescriptions, patient referrals to specialists, sick leave reductions... All this, of course, unless we're fired beforehand!"

Branislava was very frustrated. She was aware that her employees were doing their jobs below their abilities, but did not know what to do.

Questions:

Suggest specific steps Dr Petrović should undertake to solve the problem.

What should Dr Petrović do if the suggested steps prove unhelpful?

Learning from anecdote: „Report: Schubert's Unfinished Symphony"

During considerable periods of time the four musicians on the oboes had nothing to do. Their numbers should be reduced and their work distributed to the rest of the orchestra. Forty violins are playing the same notes. This seems to be an unnecessary duplication, so this part should be drastically cut. If you want more volume, an electronic amplifier should be used.

There is no need to repeat on the horns the passage already played by the string instruments. If these parts were eliminated, the concert would be reduced to 20 minutes. If Schubert had worried about these problems, he probably would have finished his „Unfinished Symphony".

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT **A Handbook for Teachers, Researchers and Health Professionals**	
Title	**Human Resource Management**
Module: 2.2	**ECTS (suggested): 0.50**
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Keywords	Human resource management, human resource planning, job analysis, recruiting and selection of personnel, employees training and development, motivation, evaluating employee performance
Learning objectives	At the end of this module, students should be able to: • define human resource management and identify its functions, • describe the steps involved in the human resource planning process, • define the term of job analysis, • describe the recruiting and selection processes, • identify methods for employees training and development, • describe methods for evaluating employee performance.
Abstract	This course covers the following topics: Fundamentals of human resource management, Staffing the organisation, Employees training and development, Personnel motivation, Employees maintenance.
Teaching methods	Teaching methods include lectures, interactive presentation of key concepts, group discussions, groups assignments, role playing for job interview.
Specific recommendations for teacher	Teaching methods include lectures, interactive presentation of key concepts, group discussions, groups assignments, role playing for job interview. Teacher should discuss the concepts and methods in comparison with the practice in SEE countries.This course takes 2 hours of lecture and 4 hours practical session including role-playing. The rest is individual work.
Assessment of students	1. Reports presented by each group during the working sessions could be considered as part of assessment. 2. A multiple-choice test containing questions from all topics, at the end of the course could be used for final assessment.

HUMAN RESOURCE MANAGEMENT

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Fundamentals of human resource management

Human resource is the most important asset of an organization, and has a crucial importance for management, as the management is the process of efficiently achieving the strategic objectives of the organization through people. Human resource management is responsible for the people dimension of the organization and is concerned with getting competent people, training them and motivating them to perform at high levels (1). Human resource management is the process that assures the utilization of the employees so that both the organization and the employees obtain the highest possible benefit.

Some authors make a distinction between *human resource management* and *personnel function*. In this view, while human resource management has a strategic role, assuming human resource policies development for the entire organization, the personnel function is supposed to have an operational role, being considered as a tool for human resource policies implementation. Thus, while human resource management is the responsibility of a special department, the personnel management is one of the duties of the managers from all levels in the organization. According to other authors personnel management is the historical term of human resource management and the change appeared with the changing roles of professionals in human resource area (2,3).

The main functions of the human resource management are staffing, training and development, motivation and maintenance.

Staffing function

In order to implement strategies and achieve the stated goals and objectives, an organization must be staffed with adequate numbers of properly trained personnel. The staffing function is a continuation of strategic planning process, when after determining how goals and objectives will be attained, the managers should determine what jobs need to be done and by whom. These activities are included in the human resource planning process that determines staffing needs. The outcome of this process will be either recruitment or decruitment (1). When acquisition of personnel is needed, the manager should

gather two types of information: information on the job and information on the persons eligible for the job, than to match skills, knowledge and abilities to required job. When manager has to sever people from the organization, he/she should engage in activities to assist and monitor exit.

The staffing function includes: human resource planning, job analysis, job description, recruitment, selection, integration of the new employee, assistance and monitoring personnel exit.

Human resource planning is the process by which an organization ensures that it has the right number and kinds of people able of efficiently and effectively performing the tasks required for achieving the strategic objectives of the organization (1,4). As organizations are dynamic, permanently under the influence of external environment and internal factors, planning should be a continuous process.

The main steps of human resource planning are: strategic objectives analysis, estimating staffing needs, assessment of current human resources, forecasting changes in the present workforce, and development of an action plan.

Strategic objectives analysis. Strategic objectives are broad statements that establish targets the organization will achieve in a certain period of time. The analysis of the current strategy determine how goals and objectives will be attained and to what extent the organization can meet its objectives given the internal strengths and weaknesses and external opportunities and threats. Commonly referred to as SWOT analysis, this managerial tool could bring information on what skills, knowledge and abilities are available internally, and where the shortages in terms of people skills or equipment may exist (1). The analysis should take into account influencing factors such as: anticipated demand for services, changes in professional practice or labour supply, development of new technologies.

Estimating staffing needs. The analysis of the objectives and of the ways in which they will be attained gives information on the number and types of the jobs needed and the skills and knowledge required for the jobs. Unless drastic changes will occur, such as reengineering initiatives, major organizational changes, human resources needs estimates could be made for a certain time period, using the established staffing ratios for most major functions. For example, for the further development of an outpatient department at a hospital, projection of the needed staff can be made (2). Using the projected volume of service and the accepted nurse staffing ratio, it can determined the number of nurses needed.

Assessment of current human resources. Assessment of current human resources is a valuable input in the human resource planning process by determining what skills are currently available in the organization and how are they used. Each organization should generate a detailed human resources inventory report listing all employees by title of the job, education, training, prior employment, performance ratings, salary level, languages spoken, abilities and specialized skills (2). Such an inventory could be also used for other activities such us internal recruitment or selecting individuals for training and development.

Forecasting changes in the present workforce. An organization will experience turnover through retirement, death, voluntary separation, etc. Based on historical data the changes in the present workforce could be forecast. For managerial positions some organizations use the replacement chart (1). This is a diagram that determines if there is within organization a sufficient managerial potential to cover future vacancies. The main information listed for each individual is: the current position, expected replacement time, and possible replacements with their potential and readiness in occupying the job.

Development of an action plan. The previous steps bring the necessary information for developing an action plan to fill the staffing needs through recruiting and hiring, transferring or enhancing the skills of existing employees by training and development. The action plan will specify: the jobs to be created, transformed or cut off, the implications at institutional level, the number of persons to be hired and specifications of their characteristics, the movement of the personnel within the organization and the training needs, the methods of sorting out the unpredictable losses, the costs of covering staffing needs and the timetable of each activity.

Job analysis and job description. *Job analysis* is a systematic examination of the activities within a job (1). This analysis involves the description of the job content (the goal of the activity, tasks to be fulfilled, duties and responsibilities, resources used, expected results), what are the job requirements (knowledge, abilities, skills required), what are the working conditions (physical environment, hazards), and the social environment (individual or group work, communication skills required, relationships to other jobs). There are three basic methods for job analysis: observation, questionnaire and interview. Observation provides firsthand information. This can be done directly or reviewing films of workers on the job. Observation can not bring exact information as people being watched act differently than in their day to day activity. The interview has an increased accuracy in assessing jobs by involving employees in analysis. In order to increase the effectiveness of this method it

is recommended a combination between individual and group interview. Structured questionnaires could also be used for gathering information about a job. The disadvantage of this method is that exceptions to a job may be left out and there is no opportunity to ask follow-up questions. Other methods that can be used for job analysis are technical conference (specific job characteristics are obtained from experts) or diary method (workers are asked to record their daily activities).

The main purpose for job analysis is to gather information in order to develop: job descriptions, job specifications and job evaluation (1).

A *job description* is a written statement of what the jobholder does, why and under what conditions. The content and format of job descriptions vary among organizations. Yet, the general *job description format* include (1,5):

Name of organization

Name of division/department

Job title

Grade of job

Job purpose

Duties to be performed

Authority and responsibilities of the job holder

Supervision given or received

Relationships with other jobs

Environmental working conditions

Special provision (e.g. confidentiality)

Terms and conditions (e.g. salary, working hours, holidays)

Job specifications states the characteristics that the jobholder must posses in order to perform the job successfully. These characteristics are identified also during job analysis and refer to the knowledge, skills, education, experience, certification and abilities needed to do the job effectively. Job description and job specifications are used in activities such as human resource planning, recruitment, selection, performance evaluation, compensation plans.

Job evaluation is the process of determining the value of each job in relation to the other jobs within organization. On the basis of job evaluation, the jobs in an organization are ranked and placed in a hierarchical order (3,6). The resulted ranking should be used in order to establish the compensation programme.

Recruitment is the process of searching and attracting potential candidates for present or anticipated vacancies. The recruitment sources could be either internal or external (2). The *internal search* attempts to identify present employees who can fill a vacancy by transfer or promotion. This method is cost effective, quick and motivating for the employees. The *external search* is done mainly by advertisements that can be placed in different newspapers, magazines, electronic sites or public places, depending on the type of the job. The main elements to be included in a *vacancy announcement* are given below (6):

Organization name
Title of the job
Location of the job
Employment duration
Description of duties
Job specifications
Salary and employment terms
Application procedure

Other external sources are employment agencies, schools, colleges, universities, professional organizations or even unsolicited applications. The selection of the recruitment source depends on the job characteristics, labour market supply, geographic workforce distribution. The success of the recruitment process is influenced by factors such as: organization reputation, the attractiveness and nature of the job, internal policies of the organization, legal requirements, and the recruitment budget (4).

Selection. The next step in acquisition of personnel is to choose from all qualified applicants for a job identified through recruiting the „right" one. This is a very important decision, as a good selection process can save costs for personnel replacement or training and can increase the work productivity. There could be considered two steps of the selection process: initial screening and final selection. Initial screening consists in gathering preliminary information about candidates and excluding those who are not suited for the job in terms of training, experience and ability. Among methods used for initial screening are curriculum vitae, intention letter, application form, letter of recommendation, employment tests.

Curriculum vitae (CV)

CVs bring information mainly on training and experience, but also give some insights about candidate personality, when looking at its clarity, stile and logic sequence of ideas (6). The information to be included in a CV is:

- personal data and characteristics (name, surname, contact details, date of birth, nationality, marital status)
- education (institutions, dates, degree or diplomas obtained)
- present position (company, location, description of main tasks)
- work experience (employment record, institutions, dates, main tasks and responsibilities)
- scientific activity (papers, presentations, publications)
- other skills (e.g. proficiency in foreign languages, computer literacy)
- other information (if appropriate, e.g. hobbies, preferences for leisure time)

Intention letter

While CV is just an inventory of the person's history regarding training and experience, the intention letter is the mean by which the candidate exposes his motivation and desire to get the job. The intention letter also talks about candidate's professional and human qualities and about his compatibility with the job. No longer than one page, an intention letter should not contain the information from CV, but has to wake up the reader interest in setting an appointment for the candidate.

Application form

There is not a general format for the application forms. Each organization has its own format, some of them requiring may be only applicant name, address and telephone number, others requesting the completion of a more comprehensive profile. In general, application forms bring less information than a CV, but they are very common, representing a standardized tool for information gathering which makes comparison between candidates easier (6). Some application forms could include statements giving the employer the right to obtain previous work history of the candidate, to dismiss him for falsing information or to end the work relationship at the employer will. If the candidate does not sign such a form his application is removed from consideration (1).

Letter of recommendation

Information about candidates could be obtained from other persons, too. Even criticized as being subjective, recommendation letters are still very common. They depend on the intention and the degree of information of the person who issues it. Usually there are requested two or more recommendation letters.

The initial screenings will shortlist the candidates for the final selection. Both shortlisted and not shortlisted candidates should be announced about their results through an official letter. The shortlisted candidates are asked to come for the final selection that can be done by employment tests or by interview.

Employment tests

Tests are used mainly for two purposes: the assessment of the candidates' knowledge, abilities and skills, and the psychological evaluation of the candidates. The second category is given more importance as many studies have shown that the employees performance is more related to their personality characteristics than to the knowledge they have. There are hundreds of tests that can be used by an organization in selection purposes. They are measuring intellect, memory, perception skills, spatial ability, motor ability, personality traits, etc. bringing information that can not be obtained from the candidate and that can make predictions on the person behaviour. Tests can be written tests or simulation tests. The last ones require the applicant to engage in specific activities and behaviours necessary for doing the job.

Assessment centres

An organization can also address for initial screening of its candidates to an assessment centre. These are specialized institutions that combine more methods in selecting candidates. All applicants are received at such a Centre for a 2-4 days period, being subjected to individual and group testing by: interviews, solving problem exercises, group discussions, role playing, personality and general ability tests, etc. In the same time it is assessed the candidates social behaviour (1).

Interview

Interview is almost universal accepted as the final selection tool, evaluating the candidates' compatibility with the job, motivation and abilities of integrating themselves in the organization. The interview gives the opportunity of clarifying the previous gathered information on the candidate and also can

test the candidate reaction under particular situations such as stress, conflicts, etc. The interview's validity and reliability are subject of criticism (1). In order to increase the effectiveness of the interview, it should be conducted by a person familiar with the interview technique and having some specific qualities: determination, discipline, self-control, tolerance, empathy, lack of prejudices. An interview should be careful prepared, paying attention to the place where it will be held, obtaining detailed information about the job and its requirements, studying applicants information gathered in the initial screening stage, planning time, developing guidelines for interview and a list of criteria to be evaluated during the interview (5,6).

Integration of the new employee. After selection, the new employee is helped to integrate in the organization, in order to become productive as soon as possible. The human resource department is responsible with enrolling new employee in benefit plans, issuing an identification badge/card. The chief of the department in which the new employee will work will take care of preparing the work place, and will delegate a supervisor to prepare and implement an orientation programme (4). The supervisor will introduce the new employee to other colleagues, will explain the organizational structure and function, will explain in detail the department specific work methods and internal norms and rules. The supervisor also helps the new employee to gain acceptance by others and will morally support him with any personal problems. Usually, in a month time the manager will meet the new employee in order to evaluate the extent to which he integrated in the organization.

Assistance and monitoring personnel exit. Sometimes the employees have to leave the organization from various reasons. The personnel exit should also be assisted and monitored. Besides activities like completing personnel records, collecting employer-provided equipment and processing final pay, a manager could involve in activities oriented to the alleviation of psychological impact of leaving the job and to assisting employees in finding employment (2). Thus, some organizations have a preretirement programme consisting in preparing employee for the psychological, emotional and financial changes in retirement. When jobs are eliminated for various reasons (changing demand, downsizing, mergers, etc.) the leaving employee should receive an earlier notice and should be helped in finding a new working place. Also, the employee could be tested for discovering abilities for other jobs and helped in the process of professional re-orientation and re-location.

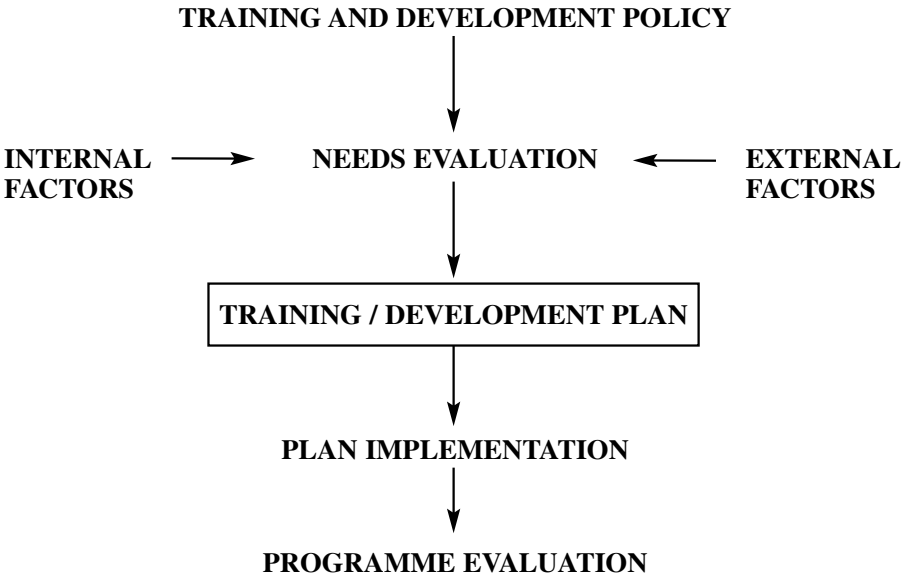
Training and development function

Training and development is a key element in helping employees to maximize their potential. The goal of training and development function is to have competent employees who possess the up-to-date skills, knowledge and abilities needed to perform their current jobs more successfully. Although there are similarities in the methods used to affect learning, the terms of education, training and development are different (6). *Education* refers to a basic teaching, a long term learning process, directed to obtaining knowledge, abilities and skills that allow individuals or groups to perform the social roles. Education is focused mainly on individual needs and also on community needs. *Training* is a learning process oriented to the acquiring of specific knowledge, abilities and skills necessary to the individuals or groups for performing a job. Training is job or tasks oriented, it has a continuous character and it might assume changing of skills, attitudes or behaviour in order to immediately adapt to the present job requirements. *Development* is a learning activity oriented rather to the future needs than to the present ones. Employee development focuses on the future jobs in the organisation and career progress for which new skills and abilities will be required.

Each organisation should have a ***continuous training*** *and* ***development programme***. Specific training and development needs are given by:

- hiring new employees,
- acquisition of new technology and equipment,
- low performance of the organisation,
- occurrence of some events with a higher frequency than usual (e.g. nosocomial infection in a hospital),
- changing demand for services,
- organisational changes.

The development of a training and development programme has the following steps (6):



Training and development policies are included in overall human resource policies of an organization and have to be in accordance with its general policies (6). Training and development programmes should take into account the training and development policies that usually state the organization's commitment of assuring to the employees the appropriate means for training in order to successfully perform their jobs.

Elaboration of a training and development programme should be preceded by *training and development needs assessment*. The training need is represented by the deficit of knowledge, abilities and skills in relation to the level required by the job or by the organizational changes (3,6).

The main information sources for needs assessment are:

- the organization – we will look at the organization's goals, structure and functioning,
- the job – what tasks have to be completed to achieve the organization's goals, what are the requirements for effectively performing the job,
- the employee – what is the level of employee's performance, what are the deficiencies he has in the skills, knowledge or abilities required to perform the job.

Training and development needs assessment has to take also in account

all internal and external factors that might contribute to the changing of the organization needs. Once it has been determined that further training and development is necessary, an action plan will be developed (6).

The structure of the training / development plans:

Training goals

Training objectives

Target groups

Training content

Training methods

Time schedule

Estimated necessary resources

Evaluation and monitoring tools

Training goals should be clearly stated and they can refer to: increasing capacity for problem solving, enhancing ability for performing specific activities, acquiring skills for performing new tasks, increasing communication skills, modifying attitudes towards change.

Training objectives should be tangible, verifiable, timely and measurable. They have to reflect the real changes in the employees knowledge, abilities, skills or attitudes.

Training content will be established in accordance with the training objectives and the level of previous training of the target group.

Training methods can be classified as either on-the-job or off-the-job training (1). *On-the-job training* method is the most used, being simple and less expensive. It is a learning by doing method, placing the employee in actual work situations and asking him to do the tasks. This method is more appropriate for jobs that are difficult to simulate or for those that can be easily learned by watching and doing. Examples of on-the-job training are:

- *apprenticeship* – is used for training in different trades where skills are so complex that can not be acquired on theoretical basis or by simulation. It consists in putting the trainee under the guidance of a skilled master.
- *job instruction training* – consists in explaining the trainees what they are suppose to do, verifying their understanding and placing them in the job under a supervisor to call upon if they need assistance.

On-the-job training has the risk of low productivity, but has the advantage of motivating workers, increasing employee morale and understanding.

Off-the-job training has a various number of techniques:

- *lectures* – designed to communicate theoretical concepts, to describe tools or to present technical, problem-solving skills,
- *seminars and workshops* – for more interactive discussions and practical exercises in which to apply theoretical knowledge,
- *simulation exercises* – in which trainees are performing different tasks in a working like situation; this also may include: case studies, role playing, group decision-making, computer based simulation, training on real equipment away from the work setting,
- *videos and films* – use media production to demonstrate specialised skills that can not be easily presented by other methods.

Developing methods can also take place on-the-job or off-the-job (1). Among *on-the-job techniques* there are:

- *job rotation* – consists in moving employees to various jobs in the organisation, either on horizontal or vertical, with the purpose of expanding their skills, knowledge and abilities. This method gives the employee an overall view on the organisation activities, turns him from a specialist to a generalist, avoids boredom and stimulates the development of new ideas.
- *working as staff assistant* – the employee works as the „shadow" of an experienced person from the next higher level. Working as an assistant, the employee has the opportunity to be exposed to the whole range of the activities in that position, he learns by performing many duties under direct supervision and get used with assuming the duties and responsibility of the higher level.
- *committee assignment* – the employee is appointed to temporary or permanent committees. This allows employee to take notice about specific organisational problems and to learn from the others example how to solve different problems and to participate in decision making.

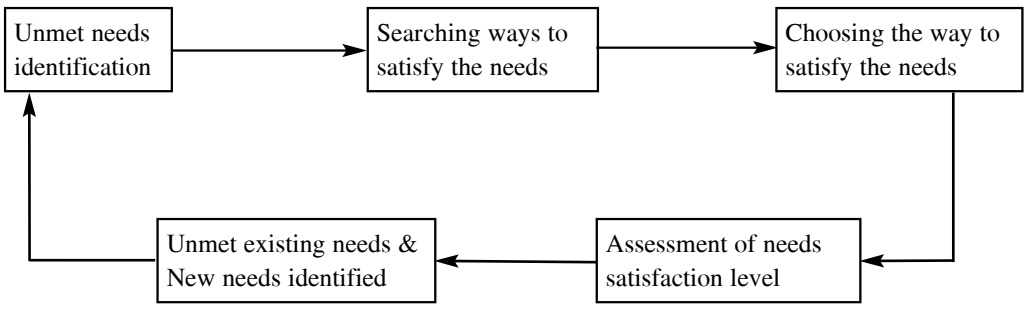
Off-the-job methods could be done by traditional forms of instruction such as lectures, seminars, simulation exercises or by modern techniques like outdoor training.

- *lectures and seminars* – they are offered for acquiring knowledge or for developing employees conceptual and analytical abilities and could be organised either in class or by distance learning.
- *simulations* – as seen above, simulations are exercises in which employees are performing different tasks in a working like situation. The most used are: case studies, role playing, decision games.
- *outdoor training* – also called wilderness or survival training, this method teach the importance of working together and involve emotional and physical challenge. The most known techniques are: white-water rafting, mountain climbing, paint-balls games or surviving one week in the jungle.

Motivation function

Motivation is a key determinant of employees performance. The concept of motivation is based on the way in which people are given attention and on the feelings that they have in relation with their work. To motivate employees means to satisfy their unmet needs, to stimulate them to work better in order to achieve the organization's goals. Unmet needs cause discontent which is reflected in employee's negative behaviour and attitudes, producing tension and low productivity.

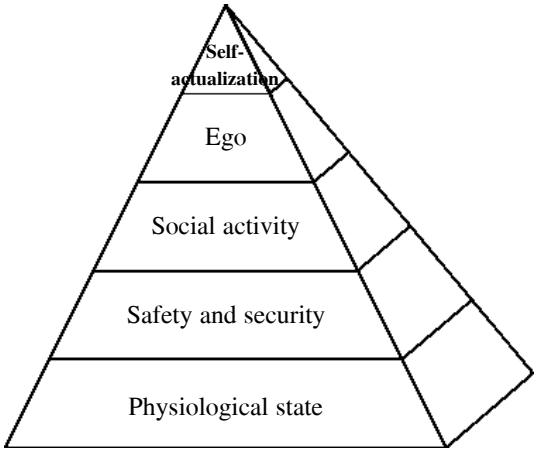
The motivation process is cyclical (2). It starts from identifying individuals unmeet needs, after that ways to satisfy the needs are searched for and the most convenient is chosen. The needs satisfaction is recommended to be followed by the assessment of needs satisfaction level, which may confirm the failure of satisfying the need, or identifies a new need and the cycle is restarted.



The motivation theories. The multitude and diversity of theories developed to explain human motivation reflects its complexity. The most important motivation theories can be divided in two categories: *content theories* and *process theories* (2,3,5). While content theories focus on „what" motivates people, process theories focus on „how" motivation is initiated and sustained. Among *content theories* there are:

Maslow's Hierarchy of Needs – considers people needs arranged in the following hierarchy (from lowest to highest): physiological, safety and security, social activity, ego and self-actualization (Figure 1).

Figure 1. Hierarchy of people needs



According to this theory, only needs not yet satisfied influence behaviour and once the needs from a level are fulfilled, the individual moves up to the next level. Primarily, an individual has physiological needs, such as air, water, food, shelter and sex are basic for an individual. Once these survival needs are met, the individual turns to the next level: safety and security, represented by needs for health insurance and other benefits that ensure protection against physical harm and deprivation. The third level of needs includes the need for belonging, friendship affection and love. Examples of ego needs are the need for independence, achievement, recognition, self-esteem and status. In the top of the hierarchy are self-actualisation needs, represented by continuing growth and development, opportunities for self-expression and self-fulfilment.

Alderfer's ERG Theory – refers to the three categories of needs: ***E***xistence needs – including material and physical needs that can be satisfied by air, water, money and working conditions, ***R***elatedness needs – that involve other people and are satisfied by social and interpersonal relationship, and ***G***rowth needs – including all needs satisfied by an individual through creative or productive contributions. Similar to Maslow's theory, people focus first on needs that are satisfied by more concrete ways.

Herzberg's Two-Factor Theory – say that job satisfaction consists of two separate and independent factors: intrinsic job factors such as responsibility and recognition which motivate when they are adequate, and extrinsic factors called also „hygiene factors" that only placate employees when are present, but they cause dissatisfaction when they are deficient. Among the hygiene factors identified by Herzberg there are: organisational policy and administration, interpersonal relationships, salary, job security, working conditions.

McClelland's Learned Needs Theory – states that people learn about their needs through life experiences and there are three major needs in workplace situations: the need for achievement, the need for power and the need for affiliation.

The most known *process theories* are:

Vroom's Expectancy Theory – based on the concept that people have preferences for outcomes and if they have a strong preference for a particular outcome, they will attach to that outcome a high valence.

Adam's Equity Theory – focus on people desire of being treated fairly and states that individuals assess whether rewards are equitably distributed within organisation by calculating the ratios of their efforts to the rewards they receive and compare them to the ratios for others in similar situations.

Locke's Goal Setting Theory – affirms the importance of goals in motivation as people focus their attention on the concrete tasks that are related to attaining their goals and persist in the task until the goals are achieved.

All the above mentioned theories are based on the *McGregor* observation of the importance of managers' attitudes about people in determining their approach to motivation. In 1960s Douglas McGregor proposed two alternative sets of assumptions that managers hold about human nature in workplaces: *Theory X* – according to which managers view people in negative ways and *Theory Y* – that argues that managers view people in positive ways. According to McGregor Theory Y assumptions are more valid than Theory X and employee motivation would be maximised by giving workers greater job involvement and autonomy.

Motivation principles (1):

- *Put the right person in the right place*. No reward or stimulating factor could increase a person's productivity if that person lacks the ability to perform the job. Matching properly the employee to the job should be an objective of recruiting and selection.
- *Managing by objectives*. People work better when their activity is goal-directed because this is challenging and it is clear to the employee what is to be done. The results are even better if individual objectives are mutually set and are in accordance with the department and organisation objectives. Continuous feedback is also important for increasing individual's performance.
- *Understanding individual needs*. Individuals are different, and each individual has its own set of needs. So, unmet needs assessment should be done for each employee.
- *Individualise rewards*. As the individual needs are different from a person to another, rewards should also be different. What motivate an individual, could not be motivating for another one.
- *Reward performance*. The best way to encourage increasing performance is to reward individuals for their performance or to relate any other reward they receive with the achievement of the organisation goals.
- *Use an equitable rewarding system*. People are concerned not only with the rewards they receive, but also with the equity of their rewards compared to what others receive. So, efforts must be made in order to ensure that the reward system is fair, consistent and objective.
- *Money is the best reward*. As money is the main reason for people to work, no other reward would be appreciated if they were not paid sufficiently to cover their basic needs.

Possible ways to increase motivation:

Job related rewards

- *Job characteristics* such as: the requirement for using various skills and talents, the requirement of completion of a whole and identifiable piece of work, the impact the job has on the lives or work of other people, a high degree of autonomy, a high degree of information received back on the effectiveness of his/her performance.
- *Job enrichment* – the worker is allowed to assume some of the tasks executed by his/her direct manager.
- *Job rotation* – the employee has the opportunity to diversify its activity and offset the occurrence of boredom.
- *Work at home* – this affords employee, especially women, to combine both their careers and family responsibility.
- *Flexible hours* – increases workers' freedom; employees assume responsibility of completing a specific work in a specific time, and this increases their feeling of self-worth.
- *Training courses*.
- *Assuring a safe, pleasant and practical working environment*.

Rewards not related to the job

- *Tangible rewards:* premiums, stocks, insurances, presents, free lunches, free snacks and coffee at the break, etc.
- *Social rewards:* free tickets for spectacles, picnics, trips, free access to company clubs, etc.
- *Acknowledgements* – diplomas, certificates, mentioning in the panel of honour, informal acknowledgements.

Maintenance / retaining function

Another function of human resource management is to put into place activities that will help retain productive employees. These activities includes: appraising employees performance, moving employees within the organization through promotion or transfer, providing employee assistance and career counseling, administering compensation and benefits, ensuring a healthful workplace and personal safety (2).

Performance appraisal evaluates an employee's work by comparing actual with expected results. It should be done at any level, from employees and managers.

Uses of performance appraisal are (6)*:*

- to collect information in order to evaluate if work results are those expected and, if not, to determine why not,
- to help decision-making in regards with compensation schemes and other benefits,
- to determine the further use of the employee (if he/she should stay at the same work place, or should be transferred, promoted, demoted or deployed),
- to evaluate training needs by identifying areas in which performance could be increased in proper training is undertaken,
- to motivate employees for working better by providing feed-back and making the results available to the others, too,
- to increase communication between employee and supervisor, allowing the opportunity to discuss the problems that are responsible for a low performance, and
- to provide information on employee assistance and counseling needs.

Performance appraisal principles are:

• Evaluation criteria should be formulated according to job description. They have to be clearly stated, easy to measure and in small number. Examples of evaluation criteria are: the degree of fulfilling with tasks, the degree of assuming responsibility, initiative and creativity, etc.

• The measuring of performance should be done against specific standards. These are established by job analysis, which gives information on the tasks that have to be fulfilled, the way in which the tasks should be performed. The performance standards cover: the quantity and quality of work, the efficient use of resources in order to maintain costs, the compliance with the time schedule, the specific requirements for the job (such as team work abilities, flexibility, communication skills, etc.).

• The appraisal should be prepared and scheduled in advance. The employee should have permanently access to his job description, which should also have attached the list of performance appraisal standards and the schedule of the periodical evaluations. Thus the employee has the opportunity to prepare in advance. On the other hand, the manager should be prepared in advance reviewing the employee's job description and his previous performance measures.

• The employee should be involved in appraisal by taking active part in the discussion, raising questions, adding his own perceptions about his work and also by a self-evaluation.

• The employee should be familiar with the purpose of the appraisal and the evaluator should behave in a way that the employee understand that the appraisal has the role of helping him and not of punishing him.

Performance appraisal methods can be classified according to the approach in: methods based on absolute standards, methods based on relative standards, and methods based on objectives (1,7).

Among the methods based on absolute standards there are:

• *Essay method* – the appraiser writes a narrative description of employee's strengths, weaknesses, potential and suggestions for improvement. This method can provide specific information, but makes difficult the comparisons between individuals.

• *Critical incident method* – looks mainly at behaviours, focusing on those critical aspects that make a difference between doing a job effectively and doing it ineffectively. The comparison and ranking of employee is difficult by this method.

• *Checklist* – the evaluator uses a list of behavioural descriptions and checks off those behaviours that apply to the employee. The list is evaluated by another person and this reduces some bias as the rater and the scorer are different persons.

• *Rating scale* – the most common method, it can be used to assess job dimension attributes such as quantity and quality of work, job knowledge, or personal traits and behaviours such as cooperation, dependability, loyalty, attendance, honesty, attitudes, initiative. For each scale there is a scoring mechanism using descriptive adjectives from „poor" to „excellent" or numerical values that often range from 1 (poor) to 10 (excellent).

• *Forced-choice method* – is a special type of checklist where the rater must choose between two or more statements, each statement being favorable or unfavorable. The appraiser will identify which statement is most/least descriptive for the individual being evaluated.

In the category of appraisal methods based on relative standards there are:

• *Group order ranking* – this requires the evaluator to place employees into a particular classification, such as „top 10". This method prevents raters from inflating their evaluation by rating everyone as good.

• *Individual ranking* – requires the evaluator to list the employees in order from highest to lowest.

• *Paired comparison* – it ranks each individual in relationship to all others on a one-on-one basis. Each person is scored by counting the number of pairs, among his colleagues, in which he is preferred member.

The third approach to performance appraisal makes use of *objectives*, being commonly referred to as *management by objectives (MBO)*. It consists in four steps: goal setting, action planning, self-control and periodic reviews. For each employee specific objectives are established jointly by the supervisor and the employee, and also realistic plans are developed in order to attain the objectives. The employee is monitoring and measures its performance, with periodic progress reviews done by supervisor.

Performance appraisal errors. The main problem with the performance appraisal methods is that all of them allow some bias (1,7). The most common errors are described below:

- *Leniency / severity errors* – the individuals within an organization are evaluated by different persons. Some evaluators are more generous than anothers, so the performance is evaluated either higher or lower than it really is, and comparisons between individuals are not reliable.
- *Halo effect* – the evaluator's general opinion on an employee is influenced by a single specific aspect.
- *Central tendency* – is the evaluator tendency of avoiding the extremes and rating everyone in the middle.

- *Similarity error* – is given by the fact that the evaluator rate other people in the same way that they perceive themselves, by projecting those perceptions onto others.
- Other errors are given by: *prejudices, different cultures, recent influencing events*.

In order to reduce appraisal errors a combination of two or more methods is recommended.

EXERCISE: Human Resource Management

Students will perform 4 exercises, after each introductory lecture. Total time requested for exercises is 4 hours.

Task 1: Small group discussion

Recommended subjects for group discussion are:

- Human resource planning advantages and limits.
- The possible recruitment sources for managerial jobs in health sector.
- How doctors in your country are best motivated.
- How performance is assessed in different organizations in your country (from students experience or after visiting some organizations and collecting information)

Task 2: Developing skills in human resources management

Recommended assignments for group work. Prepare the following:

- Job description
- Write the job advertisement
- CVs and intention letters
- Find different blank application forms from different organizations and compare them.

Application form which is most preferred overall by the class.

Develop a training plan for middle-level hospital managers.

Task 3: Web-wise exercises

Search the web to identify current job opportunities:

http://www.careermosaic.com

http://www.occ.com

http://www.who.ch

Look also for other sites.

Task 4: Role play

Job interview:

Choose up to 7 applicants for a certain job who will submit their CVs and intention letters for applying to a job. A small group (4-5 persons – the interview commission) will shortlist 2-3 candidates for interview. Than the interview will be conducted and it will be chosen the best person for the job. The other persons in the class will discuss at the end the positive and negative aspects observed during the interview.

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Recommended readings

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Information Systems Management**
Module: 2.3	**ECTS (suggested): 0.25**
Author(s), degrees, institution(s)	Adriana Galan, IT Specialist Part-time senior lecturer at the University of Medicine and Pharmacy, Department of Public Health and Management, at postgraduate level
Address for Correspondence	Institute of Public Health Bucharest 1-3 Dr. Leonte Street 76256 Bucharest Romania Tel: (4021) 2249228 / ext.188, Fax: (4021) 3123426 E-mail: agalan@ispb.ro
Keywords	Information system, management of information system, decision making, problem solving, management cycle
Learning objectives	At the end of this course, students should: • identify the basic concepts of the management of information systems; • be able to describe the existing types of applications in the medical field; • identify the need and role of information in a managerial cycle; • be able to make the difference between the types of decision and the information system required by each type of decision; and • learn the medical fields where an information system can offer support.
Abstract	This course covers: Definitions and basic concepts, Existing types of applications in the medical field, Managerial cycle and information support, and Types of decisions and the related information systems. Recommended readings are also given. At the end of this course, the case study is proposed to be solved.
Teaching methods	Teaching methods include lecture, interactive presentation of key concepts, overheads or PowerPoint presentation. Case study will be solved in small groups (4-5 persons) and an overhead will be presented by each group with their findings.
Specific recommendations for teacher	It is recommended that this module is organized within 0.25 ECTS credit. The work under supervision is consisting from lecture (2 hours), case study reading (1 hour), and case study solving (1 hour), while individual work is related to review literature to prepare an essay (3,5 h).
Assessment of students	1. Reports presented by each group can be considered as assessment. 2. An essay on the types of information systems used in their own organizations (functions, what type of decisions are supported etc.)

INFORMATION SYSTEMS MANAGEMENT

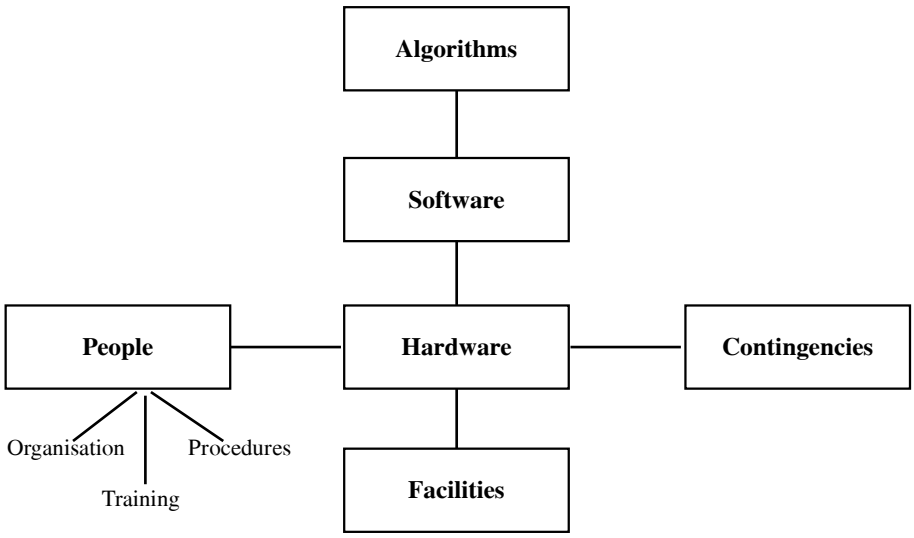
Adriana Galan

Definitions and basic concepts

There are many definitions of information systems, based on the definition of a general system, representing a group of interrelated elements organized to achieve a common purpose. Out of these definitions, here are presented:

- *Information System* represents that type of system trying to solve the problems in an appropriate manner, able to generate the information at right time and place, in an understandable format, in order to be used in the managerial process.
- *Information System* is a special class of system whose components are people, procedures and equipment that work interdependently under some means of control to process data and provide information to users (1). Figure 1 summarises this definition:

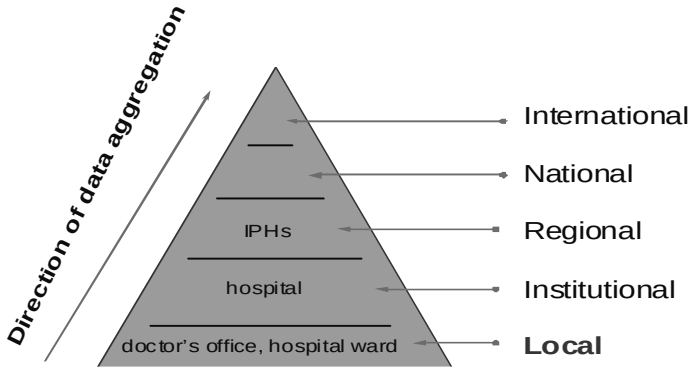
Figure 1. System Engineering Components (2)



Management of Information Systems (MIS) are orderly methods of gathering, storing, organizing, analysing, and reporting data in a manner that is meaningful, useful, and quickly to retrieve. The direction of data aggregation is given on Figure 2.

MIS provides a foundation upon which a hospital / health organization can develop its information resources and enhance decision-making, strategic planning, and quality of clinical services.

Figure 2. Levels of Information Systems



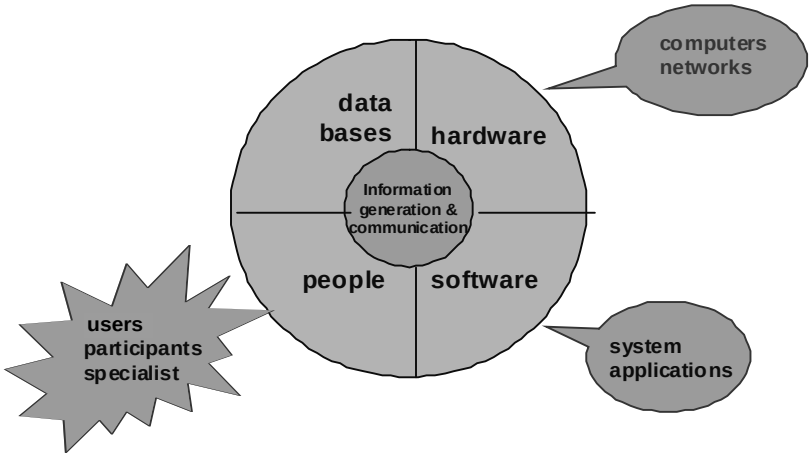
Basically, any Information System is working with three key concepts:

- **data**: facts obtained by observation, counting, measuring, weighing from the surrounding environment (for example: patient temperature is measured as 39.5°C)
- **information**: follows that data which have been analysed, summarized or processed in some fashion to produce a message or a report; becomes information only if it is understood by the recipient (for example: T=39.5°C, headache, photophobia (possible meningitis)
- **knowledge**: represent the result of combining meaningful information

There is not a clear distinction between the three concepts, many times information can be considered as data for the higher level inference.

Components of Health Information System are given on Figure 3.

Figure 3. Health Information System



Existing types of applications in the medical field

The main types of IT applications in the medical field developed worldwide are (3):

Patient registration and hospital admission systems

The main functions of this application are:

- *data collection*: demographic, clinical and financial
- *reporting*: generates different types of documents based on data analysis and also administrative reports
- *operations management*: keep track of patient transfers and discharges

Patient accounting

- *prices of provided services per patient*: attach a price for each service received by a patient. The price can be established according to different criteria:
  - based on the range of services contracted with the insurer
  - based on DRG system (Diagnosis Related Groups)
  - based on the type of patient: inpatient, outpatient, emergency

Depending on the type of contract between providers and insurer, the output of this application can be some other unit than the monetary one (e.g. number of points, credits, etc.). The insurer can further transform these units into monetary ones.

- *patient bill*: calculate the patient bill to be sent to the insurer
- *electronic data interchange*: between the health care provider and the insurance

Financial management

- *Payroll system*: calculate employees' workload, calculate the taxes, produces the salaries forms together with control reports, forms for tax declaration
- *Staff registry*: manages a history of employment for each employee (payment reports, licenses, continuous education training, etc.)
- *Assets registry*: manages the registry of organizational assets (fix properties, physical site, depreciation planning etc.)
- *General financial registry*: collect data from all financial applications having as result the financial balance sheet (debts and credits) and the annual financial management

Patient registry and management of care

- *Patient index*: collects and manage a summary of patient record for all in-patients and out-patients
- *Procedures and diagnosis coding*: check the accuracy of disease codification according to international codification system, build the DRG classes
- *Monitoring the transfers*: monitor the link between clinical wards and ancillary departments (radiology, pharmacy, labs, etc.)

Pharmacy systems

Physician's orders for drugs are registered. The system is monitoring each patient: *what* and *when* must receive the drugs. Also keeps a drug inventory and can act as a warning system for the incompatibility of 2 or more drugs for a patient.

Management of primary care patient

Big efforts were done in the last decade for developing this system due to the increasing weight of ambulatory care. Some functions can be mentioned:

- *Visit scheduling*
- *Patient registration*
- *Medical records and monitoring the consultations*
- *Financial module*
- *Pharmacy module*
- *Communication module (electronic data interchange)*

Electronic Medical Records (4)

Very modern in USA, even at early stages of implementation, is the concept of „Electronic Medical Record" (EMR). The traditional medical record has been exposed to a rethinking process, in order to provide the needed information for:

- *Clinical Care*
- *Billing*
- *Research tool*
- *Communication tool*

Communication was a key issue in these modern clinical systems, unlike the old clinical systems. EMR must be accessible for all the clinical care providers of a patient (family doctor, outpatient clinics, hospitals), but can be accessed by the patient himself. At the same time, clinical databases are a powerful research tool. Another important step forward is represented by the accessibility of EMR via Internet.

What are the main information areas in an EMR?

- *ID*
- *History of Present Illness*
- *Current Medication*
- *Past medical history*
- *Past surgical history*
- *Family history*

- *Physical examination*
- *Laboratory Database (including images)*
- *Procedure note*
- *Problem list (assessment)*
- *Plan (diagnostic / therapeutic)*

Managerial cycle and information support

Information systems can essentially contribute to increase the manager's degree of confidence in the validity of alternatives that are the basis of organizational strategic decisions. Also within the health units, information can represent a valid support for problem solving, like:

- cost control and productivity enhancement (*financial information systems*)
- medical quality assurance and outcomes assessment (*clinical information systems*)
- health care organizations must frequently monitor and evaluate their performance, both for internal purposes and to meet external regulations and accreditation criteria (*administrative information systems*)

The basic management process in any health care organization can be described in terms of a cycle that includes the following components (5):

- establish goals and objectives
- estimate demand for services
- allocate resources to meet demand
- control the quality of performance
- evaluate programs impact

Cycle is repeated after each evaluation. Information management should play an important role in each element of this basic management cycle.

Examples of types of information that can help decision making in each category, can be described as follows:

1. *Establishment of institutional goals and objectives*

- problem indicators, direct and indirect (direct: morbidity and mortality data, social indicators, economic data on the community;

indirect: data on personal health habits of members of the community)

- data on services being delivered by other community health organizations
- available resources

2. *Demand estimation*
   - historical data on utilization of health services
   - demographic data
   - community projections
3. *Resource allocation*
   - work force data
   - financial information
   - short-term demand forecasts
4. *Performance and quality control*
   - output measures (statistics: number of inpatient days, patient visits in outpatient department, number of delivered procedures etc.)
   - quality control data
   - work sampling and measurement
   - medical audit
5. *Evaluation of program impact*
   - changes in problem indicators
   - cost-benefit analysis

Types of decisions and the related information systems

From the informational point of view, Herbert Simon (6) has described two types of decisions:

- *programmed (structured) decisions* - these are periodical decisions, repetitive and routine;
- *non-programmed (unstructured) decisions* - these are occasional decisions, irregular and must be treated in a new manner each time they occur.

Simon classification is based on the manner in which a manager deals with existing problems. A well-designed information system is obviously influenced by the periodicity or non-periodicity of decision.

There are two approaches for an information system to meet the need of non-programmed decision making process:

- to organize special studies in order to collect necessary information, involving a big effort and being time-consuming; costs and benefits of this approach must be analysed in advance;
- to be operational a general information management system, where relevant information have to be only retrieved and analysed.

Robert Anthony (7) has developed a theory that represents the basis for the process of analysing and planning the information systems. He described the managerial activity consisting of three categories, arguing that these categories are activities sufficiently different to require the development of different information systems (Figure 4).

Strategic planning - is the process of deciding on organizational objectives, changes of objectives, resource allocation to attain these objectives and on policies that govern the acquisition and use of these resources.

The major problem of this type of activity is to predict the future of the organization and its environment. This level typically involves a small number of high-level people who operate in a very creative way.

The complexity of problems that arise at this level, as well as the non-routine way in which they are handled, make it difficult to design an adequate information system. Usually, in this planning process aggregated information is needed, most often obtained from external information systems. At this level most of the decisions are unstructured (see definition above) and irregular.

Management control - the process by which managers assure that resources are obtained and used effectively and efficiently for the accomplishment of the organization's objectives.

This type of activity involves interpersonal interaction. It also takes place within the context of the policies and objectives developed in the strategic planning process. The main goal of management control is the assurance of effective and efficient performance. The relevant information for this level is mainly obtained during the human interaction process.

Operational control - represents the process of assuring that specific tasks are carried out effectively and efficiently.

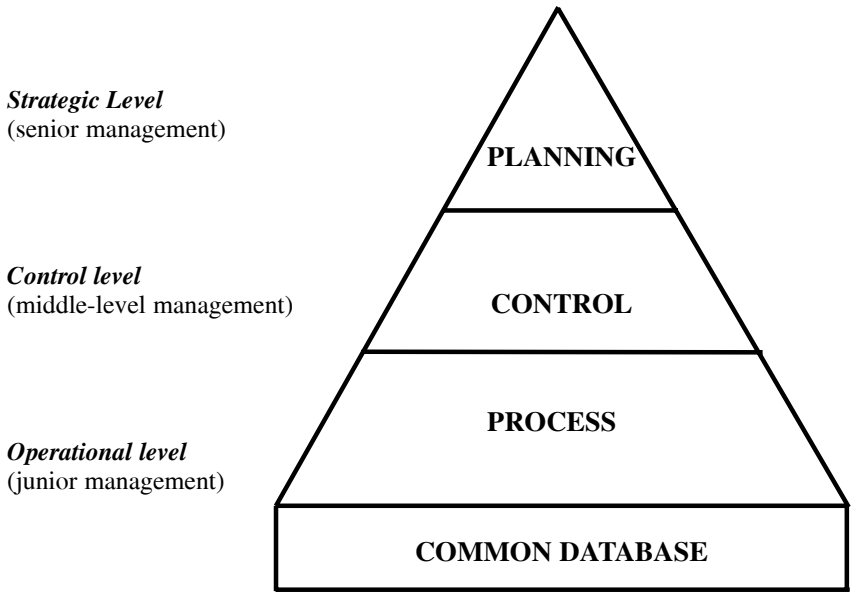
The basic distinction between management control and operational control is that operational control is concerned with tasks, whereas management control is mostly often concerned with people.

This level requests clearly defined information for very specific tasks. Information must be detailed, accurate and is obtained mainly from inside the organization.

For each managerial level described by Anthony, a specific information system must be designed.

Each level of decision-making process corresponds to a different administrative level of the health system. The *Operational level* corresponds to the health care units (hospitals, primary care units, ambulance, etc.) where huge amounts of detailed and updated information exist and are reported to the upper levels. The *Control level* corresponds to the Local Health Authorities (for instance, in Romania the District Public Health Authorities exist in each of the 42 districts, one district covering 500,000 inhabitants on average), information being here aggregated for the local level. The *Strategic level* corresponds to the Ministry of Health, where information is highly aggregated for the national level, but often being rather old (a 2-years time lag).

Figure 4. Hierarchical model of decision-making process proposed by Anthony (7)



Within the managerial process of decision-making, an information system can offer support for the following areas (8):

• *Medical quality assurance and outcomes assessment*. Clinical information abstracted from patient medical records provides the basis for health professionals in peer review systems to assess diagnosis and treatment practices. Such information must be readily accessible and retrievable from a central patient data file.

• *Cost control and productivity enhancement*. Such systems require the ability to integrate clinical and financial information system. Computerized information systems offer the possibility for providing cost analysis and productivity reports in order to improve the efficiency of operation.

• *Utilization analysis and demand estimation*. Such systems should be able to provide current and historical data on utilization of health services. These data assist in current analysis of utilization of resources and also provide a basis for predicting future demand for services.

• *Program planning and evaluation*. Information obtained for the previous above-mentioned domains serves as the basic input for management decisions related to evaluation of present programs and services. When combined with projections about future changes in the demographic characteristics of the population and other external information about the service market, the information system can be an important resource for planning future programs and services.

Simplification of reporting. Information processing costs consume an important proportion of the budget of a complex health organization. On the other hand, external reporting requirements are growing exponentially. Therefore, an important goal for an information system is to simplify the preparation of these various reports, often a difficult repetitive task.

EXERCISE: Management of Information Systems

Task 1: Recognizing different types of information system, and their importance in decision-making process

The purpose of the exercise is enabling students to recognise different types of information systems, and their importance in decision-making process. Students are asked to split in small group, in order to read this case study, and then discuss, following suggestions given below (30 minutes for reading the case study, 60 minutes for work in a small group, 30 minutes for discussion in whole group). Total time for exercise: 2 hours.

CASE STUDY* - An usual manager's working day

By January 15, 2002, the user of different types of information systems was doctor Escu, the director of „Wonderland" District Public Health Authority (DPHA). Doctor Escu has the responsibility of developing and implementing health policies at „Wonderland" district level.

Doctor Escu lives in a neighbourhood located far enough from DPHA site. In the morning, after waking up, he listen first the radio news in order to decide if he would rather use his own car or the DPHA car. Because bad weather was forecasted, he decided to use the office car. On the way to DPHA location, the driver didn't give priority to the pedestrians, so that a policeman stopped him. Apart from the fine, he was also registered in the police files.

Once arrived at DPHA, doctor Escu turns on the computer and check first his meeting's schedule for the day, file already updated by his secretary. After reading his messages, he answers himself to two of them. For the rest of the messages, he forwards the messages to the secretary and asks her to answer.

After that, he invites the head of Human Resources Department and the economic manager to try to solve together the problem of the hundred junior physicians applying for a job in the district.

At noon, a meeting with a foreign expert's team was scheduled. The foreign experts were willing to help the DPHA to implement an intervention project to reduce some risk factors in order to improve the health status of „Wonderland" district population. The experts were bringing a software for modelling and simulation of the impact of reduction of risk factors on health. Doctor Escu has also invited to attend this meeting the head of „Health Status Evaluation" Department, as well as public health specialists and epidemiologists.

* Case study adapted by Adriana Galan, based on a case study developed by G.Lucas Jr.

Around 6 PM, doctor Escu leaves the DPHA, and on the way back he stops to a supermarket to make some shopping.

Once arrived at home, he watches the TV news, then he reads the financial report for the previous month in order to prepare the next day meeting with the economic manager. Finally he decides to go to bed because he felt very tired.

Please observe carefully the activity of doctor Escu during the whole working day and determine what type of information systems he was using in each circumstance. For each information system you discovered, please mention for what type of decision it was useful (use Anthony theory and mention if the decision was programmed or non-programmed).

Moment of the day	**What type of information system was used**	**Type of decision**
During the morning		
During afternoon		
During the evening		

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Recommended Readings

In BMJ collection (http://www.bmj.com): search/archive keywords: HealthCare Information Systems

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In National Academy Press books collection (accessible at URL http://www.nap.edu) search all texts under title HealthCare Information Systems

- Committee on Enhancing the Internet for Health Applications - Networking Health: Prescriptions for the Internet (2000, 388 pp.)
- Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure, National Research Council - For the Record: Protecting Electronic Health Information (1997, 288 pp.)
- Edward B. Perrin, Jane S. Durch, and Susan M. Skillman - Health Performance Measurement in the Public Sector: Principles and Policies for Implementing an Information Network (1999, 192 pp.)
- Richard S. Dick, Elaine B. Steen, and Don E. Detmer - The Computer-Based Patient Record: An Essential Technology for Health Care, Revised Edition (1997, 256 pp.)
- Maria Hewitt and Joseph V. Simone - Enhancing Data Systems to Improve the Quality of Cancer Care (2000, 176 pp.)
- Committee on Quality of Health Care in America - Crossing the Quality Chasm: A New Health System for the 21st Century (2001, 364 pp.)

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Financing of Health Care**
Module: 2.4	**ECTS (suggested): 0.50**
Author(s), degrees, institution(s)	Doncho Donev, MD, PhD Institute of Social Medicine, Joint Institutes, Medical Faculty, University of Skopje 50 Divizia no.6, 1000 Skopje, Republic of Macedonia Jadranka Bozikov, MPH, PhD Andrija Štampar School of Public Health Medical School, University of Zagreb Rockefeller St. 4, HR-10000 Zagreb, Croatia
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Keywords	Sources for financing of health care; taxation; health insurance; health care costs; health expenditures; hospital costs; Europe, South Eastern; health planning
Learning objectives	At the end of this module students and health professionals should be able to: • identify common reasons for increasing trend of expenditures in developing ad developed countries; • compare inequalities in global health spending; • explain the purpose and the scope of each source for financing of Health Care (State budget, Health Insurance, External sources, Private sources); and • describe and justify two basic principles: efficiency and equity in Health Care delivery.
Abstract	Financing of health care and making balance between revenues and expenditures for health care is very intricate problem and source of serious concerns in practically all countries in the world. Permanent increasing of elderly, patients with chronic diseases, use of expensive health technologies and their non-critical implementation, and some other factors are causing increase of the expenditures for health care. Big inequalities are recognized among countries in global health spending and many health system reforms are characterized by transformation from central planning to market-based. There are four basic sources for collecting of financial resources for health care: taxation, social health insurance, private sources and external sources of financing. They are presented in different proportions among countries. Each source for financing of health care has its own specificities, strengths and weaknesses, and each may be appropriate alone or in combination with other, which depends on various circumstances and environment.
Teaching methods	Teaching method will include combination of introductory lectures, group work and discussion followed by group report presentations and overall discussion, as well as practical individual work assignment.

Specific recommendations for teacher	This module to be organized within 0.50 ECTS credit. Beside supervised work, students, as a practical work assignment, should collect some specific indicators (HFA Database and other sources) and to prepare a seminar paper about the source(s) of financing of health care in their respective countries.
Assessment of students	The final mark should be derived from assessment of the theoretical knowledge (oral exam), contribution to the group work and final discussion, and quality of the seminar paper.

FINANCING OF HEALTH CARE

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Adequate financial resources are a prerequisite for the operation of health services and the delivery of care. Resources can be released if steps are taken to focus attention on the quality of care and on planning and managing the whole health sector, weighing up the relative values of health promotion, disease prevention, diagnosis/treatment, rehabilitation and care, as well as to fund some of the new investments that will be required to apply more effective (but often expensive) new technologies. Sources for financing of health care vary from country to country, ranging from tax-based to insurance-based systems. There is considerable debate about how best to fund services so as to maintain universal access and financial sustainability. Most often, a mix of these systems is seen. Available resources for health care should be allocated in the light of a society's needs and priorities. Choices have to be made between geographical areas and services, and between particular forms of treatment, and whether to provide innovative or expensive procedures. The health for all policy framework for the WHO European Region „Health 21" address the issue of funding health services and allocation of resources as target 17 in the following way: „By the year 2010, Member States should have sustainable financing and resource allocation mechanisms for health care systems based on the principles of equal access, cost-effectiveness, solidarity, and optimum quality" (1).

Financing of health care means mechanisms by which money is mobilizing (raising or collecting revenue from individuals, groups and firms) to fund health sector activities and to pay for the operation of the health system (2). Financing of health care is a source of serious concerns in practically all countries in the world. The question of how to generate sufficient revenues to pay for health care worries policy makers in the countries whose total health care expenditures are 1-3% of their GDP, as well as those who are spending more than 10% of GDP for health care. Countries of the OECD accounted for less than 20% of the world's population in the year 2000 but were responsible for almost 90% of the world's health spending. The African Region accounts for about 25% of the global burden of diseases but only about 2% of global health spending (3,4,5). Shortage of funds for health care affects both, the countries who are spending less then 10 US$ per capita per year and the countries who are spending more than 2000 US$ per capita per year (Table 1).

Table 1. Inequalities in global health spending in 2001 (3,4,5)

Although the causes are different, the problem is the same: how to balance revenue and expenditure for health care? It is not only the question of collecting of financial resources and pooling of funds but also of purchasing of services and reallocation mechanisms i.e. of transfer of revenue to service providers who deliver the health care to population for which the funds were pooled. The level of financial resources required to operate a health service is impossible to specify in absolute terms. Certainly the amount should be affordable by the country and enough to meet the needs of both health promotion and the provision of effective and high quality care. A comparative analysis of current European experience suggests that 7-10% of GDP may provide for a reasonable spread of health system capacity and performance, dependent of course on an adequate overall level of national GDP. Furthermore, in most countries expenditure trends over time ought to show an increase in the share of resources allocated to health promotion and disease prevention, and to primary health care (PHC). This range is indicative only and individual countries must determine the best level based on their economic resources, their health experience, and their need for health promotion and the provision of effective and high-quality care (1).

Most countries feel constant pressure because expenditure is increasing and resources are scarce. Policy-makers have three options: containing costs, increasing funding for health services or both. Concern about an expenditure crisis in health care has led to the introduction of major changes in how health care is organized and financed. Cost containment has been driving health policy discussions in industrialized countries since the 1970s (6).

The problem of scarce resources is particularly pronounced in South Eastern European (SEE) countries that have faced many difficulties in the process of transition in 1990-ties, after the breakdown of former communist/socialist system. Social and economic transition in Central and Eastern European (CEE) and the former Soviet Union (FSU) countries included health system reform characterized by transformation from central planning to market-based. This has included reducing of direct state involvement and introduction of market forces and competition through decentralization, privatisation and organizational reform of health care, which emphasized the shortage of the resources for health care (7) (Table 2).

Table 2. Health care expenditures in USA and European countries in 2000 (7)

Country	Total expenditure on health as % of GDP	Per capita total expenditure		Per capita GDP	Public health expenditure	Private expenditure
		in US $	in int. dollars	in int. dollars	(% of total)	(% of total)
United States of America	13.0	4499	4499	34,637	44.3	55.7
European countries*						
Israel	10.9	2,021	2,338	21,552	75.9	24.1
Switzerland	10.7	3,573	3,229	30,161	55.6	44.4
Germany	10.6	2,422	2,754	25,996	75.1	24.9
France	9.5	2,057	2,335	24,702	76.0	24.0
Belgium	8.7	1,936	2,269	26,054	71.2	28.8
Sweden	8.4	2,179	2,097	24,819	77.3	22.7
Denmark	8.3	2,512	2,428	29,143	82.1	17.9
Portugal	8.2	862	1,469	17,981	71.2	28.8
Italy	8.1	1,498	2,040	25,308	73.7	26.3
Netherlands	8.1	1,900	2,255	27,783	67.5	32.5
Austria	8.0	1,872	2,171	26,970	69.7	30.3
Norway	7.8	2,832	2,373	30,344	85.2	14.8
Spain	7.7	1,073	1,539	20,071	69.9	30.1
Armenia	7.5	38	192	2,546	42.3	57.7
United Kingdom	7.3	1,747	1,774	24,462	81.0	19.0
Czech Republic	7.2	358	1,031	14,236	91.4	8.6
Georgia	7.1	41	199	2,768	10.5	89.5
Hungary	6.8	315	846	12,493	75.7	24.3
Ireland	6.7	1,692	1,944	28,944	75.8	24.2
Finland	6.6	1,559	1,667	25,122	75.1	24.9
Estonia	6.1	218	556	9,123	76.7	23.3
Kyrgyzstan	6.0	16	145	2,426	61.7	38.3
Lithuania	6.0	185	420	6,941	72.4	27.6
Poland	6.0	246	578	9,590	69.7	30.3
Latvia	5.9	174	398	6,888	60.0	40.0
Slovakia	5.9	210	690	11,654	89.6	10.4
Belarus	5.7	57	430	7,598	82.8	17.2
Turkmenistan	5.4	52	286	5,269	84.9	15.1
Russian Federation	5.3	92	405	7,621	72.5	27.5
Turkey	5.0	150	323	6,455	71.1	28.9
Ukraine	4.1	26	152	3,689	70.1	29.9
Kazakhstan	3.7	44	211	5,677	73.2	26.8
Uzbekistan	3.7	30	86	2,333	77.5	22.5
Tajikistan	2.5	4	29	1,154	80.8	19.2
Azerbaijan	2.1	14	57	2,676	44.2	55.8

South Eastern European countries (SEE)*						
Slovenia	8.6	788	1,462	16,927	78.9	21.1
Croatia	8.6	353	638	7,390	84.6	15.4
Greece	8.3	884	1,390	16,843	55.5	44.5
Macedonia	6.0	106	300	5,001	84.5	15.5
Serbia and Montenegro	5.6	50	237	4,242	51.0	49.0
Bosnia and Herzegovina	4.5	50	319	3,404	69.0	31.0
Bulgaria	3.9	59	198	5,021	77.6	22.4
Moldova	3.5	11	64	1,802	82.4	17.6
Albania	3.4	41	129	3,727	62.1	37.9
Romania	2.9	48	190	6,475	63.8	36.2

* European countries here means countries belonging to WHO Office for Europe with population above one million excluding SEE countries (i.e. members of PH-SEE Network) that are presented separately. Source: WHO (7).

** The international dollar is a common currency unit that takes into account differences in the relative purchasing power of various currencies. Figures expressed in international dollars are calculated using purchasing power parities (PPP), which are rates of currency conversion constructed to account for differences in price level between countries.

Developing countries who were hardly providing funds for essential health needs were seriously affected with the economic crisis, which started in 1970s. Those countries were forced to further decreasing of already scarce funds for health care. Continuous debts, dependency for import of drugs, vaccines, equipment and other supplies with very high and continuously increasing prices led to hopeless situation in most of the developing countries. Much progress has been made in rationalizing the choice of priority interventions since the time of standard „minimum package" of the early 1990s. Prioritising cost-effective interventions (preventive, promotive, curative and rehabilitative), that gives the most value for money, is all the more important as new funds become available to the health sector (3-5,8,9,10,11,12).

Developed countries, especially USA and some Western European countries (Table 2), recognized very fast increase of the required funds for health care and came to conclusion that the health care expenditures are threatening further economic development and that it is necessary to stop those trends or even to tend to decrease those expenditures. That is why the most of the developed countries are reconsidering the ways of financing of health care, taking into consideration the reasons, which caused misbalance among needs and available funds. In the US health care delivery system, faced with an exponential increase in expenditures during the second part of the 20th century, was forced to explore ways to reduce costs and, at the same time, maintain a high quality of care. Managed care emerged as one of the answers and quickly became one of the predominant health care delivery models (13).

The most common external reasons and pressures for increasing trend

of expenditures for health care from outside the health care system, which cannot be directly controlled by the providers of health care services, are the changes in all fields of life and human activities, i.e. economy, health, sociology, culture, demography and political sphere. Demographic changes with growth and ageing of the population, societal changes and health problems related to poverty and life-styles (smoking, poor diet, drug abuse, AIDS), as well as changes in health status of the population objectively influenced the increase of the expenditures for health care because the permanent increasing of elderly proportion and dependency ratio, and patients with chronic diseases requiring long term care increase the needs and demands for health care and use of expensive health technologies. Political changes, often followed by broadening of the scope of social rights to the population, have influenced to increasing coverage of the population with health insurance and health care services. From the other side, there are some internal factors within the health care industry, which might be controllable by health care providers and management structures, related to increases in technology and labour costs, inefficient use of available resources, insufficient preventive services and the practice of defensive medicine. The costs for introducing new drugs in increasing number and non-critical implementation of new technologies caused increase of the expenditures for health care, even though it doesn't belong in the category of the objective reasons (3,5,8) (Table 3).

Table 3. Main reasons for increasing trend of health care expenditures (3,5,8)

EXTERNAL FACTORS (Outside the Health Care System)	**INTERNAL FACTORS** (Inside the Health Care System & Industry)
• Demographic transition (growth and ageing of the population) • Epidemiological transition - changes in the health status (increase of chronic conditions and non-communicable diseases) • Societal and cultural changes and health problems related to poverty and life-styles (smoking, poor diet, drug abuse etc.) • Political and environmental changes (rising expectations for health care rights, increased insurance and health care coverage) • Economic changes and inflation	• Rapid innovations / changes in technology and non-critical implementation of new technologies • Introducing new drugs in increasing number • Developments in science (accurate genetic tests and the genetic make-up of an individual) • Increases in labor costs (further specialization and sub-specialization of manpower in complex institutions of labor-intensive or „handicraft" industry) • Inefficient use of available resources (inappropriate allocation to primary health care vs. hospital care) • Insufficient preventive services (the practice of defensive medicine)

All those changes influenced the ways and extend of financing of health care, but, in most of the cases, an individual and a family were not able to carry the risk and burden of disease. Because of that the State and the Government were pressed to take active role in providing health care of the citizens by directing a part of the budget funds for health care or by introducing compulsory health insurance. Nevertheless, within the new contemporary conditions the sources for financing of health care and relationships among them are often changing. There are big differences and variations in proportions of public and private sources of health care expenditures, both among developed (USA, European and other) countries and among SEE and FSU countries (7) (Table 4).

Table 4. Sources of public and private health care expenditures in USA and European countries in 2000 (7)

Country	Sources of public health expenditure		Sources of private health expenditure
	Social health insurance (%)	External resources (%)	Prepaid plans (%)
United States of America			
European countries*			
Israel	25.8	0.4	
Switzerland	72.7		42.4
Germany	91.7		5.3
France	96.8		53.1
Belgium	82.1		6.8
Sweden			
Denmark			8.9
Portugal	7.2		5.5
Italy	0.1		3.4
Netherlands	94.1		76.7
Austria	61.0		23.2
Norway			
Spain			11.7
Armenia		4.9	
United Kingdom	11.2		16.9
Czech Republic	89.4		
Georgia	14.6	9.7	
Hungary	83.2		0.8
Ireland	12.9		23.8
Finland	2.4		12.0
Estonia	86.0	0.5	4.1
Kyrgyzstan	5.8	2.4	
Lithuania	9.7		
Poland			
Latvia	65.4	0.7	
Slovakia	96.8		
Belarus		0.1	
Turkmenistan	18.9	0.8	
Russian Federation	24.5	4.4	4.3
Turkey	28.4	0.1	0.1
Ukraine			
Kazakhstan	26.4	2.4	
Uzbekistan		1.3	
Tajikistan		19.5	
Azerbaijan		8.8	

South Eastern European countries (SEE)*			
Slovenia	82.0	0.8	48.9
Croatia	96.5	0.4	
Greece	36.9		4.9
Macedonia	87.5	3.7	
Serbia and Montenegro		6.2	
Bosnia and Herzegovina		2.0	
Bulgaria	16.0	18.0	
Moldova		13.9	
Albania	26.1	12.6	36.4
Romania	13.3	1.1	

* European countries here mean countries belonging to WHO Office for Europe with population above one million excluding SEE countries (i.e. members of PH-SEE Network) that are presented separately. The countries are sorted by the percentage of their total expenditure on health. Source: WHO (7).

Markets in Health Care

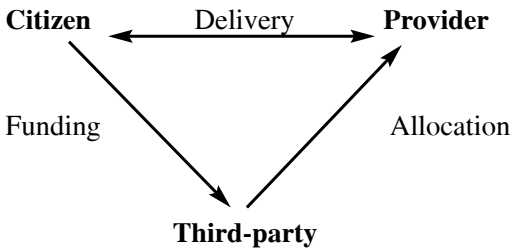
Available evidence from both western and eastern Europe indicates that unfettered markets are not compatible with the nature of health as a social good. Market mechanisms in health care are likely to be more successful, financially and operationally, if they are focused on hospitals and physicians; in contrast, efforts to create competition among multiple private insurers or to require increased co-payments from patients have been notably less successful.

For the application of market mechanisms to service providers to work well, the State needs to steer and regulate these relationships by creating or improving market competition, opening up choice of provider in public health or insurance financing „money follow the patient", quality regulation and contracting with providers. While the mix of public/private ownership of provider institutions varies greatly across Europe, both efficiency and equity require consistent and stable State regulation (14,15).

The health care triangle

The provision and financing of health care can be simplified as an exchange or transfer of resources: the providers transfer health care resources to patients and patients or third parties transfer financial resources to the providers (Figure 1).

Figure 1. The health care triangle (6)



The simplest form of transaction for a good or service is direct payment. The consumer (the first party) pays the provider (the second party) directly in return for the good or service. Health care systems have developed in which a third party offers protection to a population against the financial risk of falling ill. The third party may be a public or private body. The development of the third-party payment mechanism in health care results in part from the uncertainty of ill health; it allows risks to be shared. However, it is also a means to achieve interpersonal redistribution. To finance health care services, the third party must collect revenue directly or indirectly from the population it protects (this may cover the whole population or a subgroup of the population such as those who are employed). This revenue is then used to reimburse the patient or the provider (6).

Basic sources for financing of health care

There are four basic sources of revenue collection for financing of health care (2,5,6):

1. Taxation (State budget)
2. Social health insurance
3. Private sources for financing (private health insurance and out-of-pocket payments etc.)
4. External resources (foreign aid, loans, grants and donations)

There is no model for financing of health care in which exists exclusively only one out of four mentioned basic sources for financing of health care. All four sources are present in practice in the developed and in deve-

loping countries. In some countries, the funds coming from the state budget are predominant at all levels of governance (from local to central), in other countries health insurance funds are basic, and in certain number of countries the most of the funds for health care are from private sources. All the funds collected by any financial method (except for foreign aid) are coming, directly or indirectly, from citizens. Each country has to decide what sources to use, and to what extend.

Revenue collection must be distinguished from fund pooling, as some forms of revenue collection do not enable financial risks to be shared between contributors, such as medical savings accounts and out-of-pocket payments. Kutzin (2001) defined fund pooling as the „accumulation of prepaid health care revenues on behalf of a population". The importance of fund pooling is that it facilitates the pooling of financial risk across the population or a defined subgroup (16).

The Role of the State in Financing of Health Care

The purpose and the scope of the sources used for financing of health care by the state are different. In general revenue financing many kinds of taxes are used to support a broad scope of government activities. Taxes can be levied on individuals (earmarked social security taxes), households and firms (direct corporate profit taxes) or on transactions and commodities (indirect taxes). Direct and indirect taxes can be levied at the national, regional or local levels. Indirect taxes can be general, such as a value-added tax, or applied to specific goods, such as an excise tax, import duties, and severance taxes on minerals etc. Most tax-based systems rely on a mix of different taxes (5,6,14).

The health system is financed through the regular government budget process. In almost every country the state through the budget provides sources for prevention and eradication of communicable diseases, hygienic control of the drinking water, food, objects for general use, sanitary monitoring over certain objects, health statistic and other activities of particular interest. In some industrial developed countries, as Great Britain, Nordic countries, France, Italy, Belgium, Greece, Spain, Portugal, as well as in the former socialistic (Central and Eastern European) countries (Poland, Albania etc.) the greatest part of the sources for health care are provided, or were provided, from the state budget, with taxes on national-central level, and from there the sources are distributed in the regions and communities where together with the local sources are used for health care of all citizens. In the developing countries the budget sources are mainly used for prevention and eradication of communicable diseases and for curing of the poorest social strata of the population (3,6).

Financing of health care through the budget has an important role and advantage in providing equal conditions in health care consumption for all citizens, independently of the social status and economic power, the place of living and working. The weaknesses of this system are that it has insufficient creativity in the process of improving of efficiency and quality of the health care, as well as the fact that the taxpayers from whom the sources are taken, have no influence in their use. In the last 10 - 15 years most of the countries with this model of financing are reconsidering this system and looking for new solutions. Some of those countries already have introduced health insurance system (Russian Federation) while other countries are still looking for solutions in direction of more rational usage of resources and for improving quality without changing the basis of financing of the system.

The Role of the Health Insurance in Financing of Health Care

The social or compulsory health insurance has a long tradition in the Western and Southern European Countries, although with variable scope of coverage of population. Some of the countries are broadening the coverage, and others are reducing it by abolition of the compulsory health insurance if the annual income is above the certain amount. The developing countries, as a rule, are introducing a system of health insurance (Latin America, South Asian countries, and most of the African countries), as well as the former socialistic Central and Eastern European countries (Bulgaria, Hungary, Poland, Czech Republic).

Social health insurance contributions are usually related to income and shared between the employees and employers, at levels that may be set nationally by Parliament (the Netherlands) or individually by each social insurance or „sick" fund. Contributions may also be collected from self-employed people, for whom contributions are calculated based on declarations of income or profit (this income may be under-declared in some countries). Contributions on behalf of elderly, unemployed or disabled people may be collected from designated pension, unemployment or sickness funds, respectively, or paid for from taxes. Social health insurance revenue is generally earmarked for health and collected by a separate Health Insurance Fund (6,14).

More and more countries decide to establish a health insurance system because the sources from the health insurance are significant additional sources for the health sector, as well as because the sources from the health insurance, as a rule, are restricted funds used only for health purpose, and for no other purposes as in the case of the budget. As an advantage of this model

of health insurance system is considered the connecting of the income with the profit in which take part the employees as well as the employer, which the most often is an organization/enterprise. Thus, if the real profits increase the sources of health insurance funds will be higher, and if the profits decrease the sources of the funds (and income of) will be lower (17). In indirect way the same happens with the tax payment from which depends the amount of the budget. The main function of the insurance contract is to reduce risk faced by the person who buys it. Risk and uncertainty are significant elements in medical care. The idea of health security „incorporates certain funding and service elements... that either protect against or alleviate the consequences of trauma, illness or accident" (17,18).

In fact, the advantage of the health insurance system is the complete implementation of two basic principles: *efficiency* and *equity* in health care providing.

The efficiency of the health insurance system depends on relationship between health insurance institutions and health care providers, in which way the obligations of both sides are precisely determined.

Health insurance funds have a long-term interest to accept funding also for some services that will bring to additional total running expenditures (measures for prevention, early detection of the diseases, usage of adequate health technologies). On the other side, the policy for participation of the users in the expenditures for the received health services tends toward decreasing of total health expenditures through reduction of the excessive and unnecessary consumption of health services. As a rule the administrative costs are low (5% of the total expenditures), although in the systems that lack adequate personnel and technology those expenditures could be even higher than 20% of the total health care expenditure.

The equity is one of the basic principles of the health insurance by which the healthy people pay for the sick people, the young people for the elderly, and the rich people for the poor people. Everyone pays a contribution proportional to his economic situation, and use the health care according his needs.

The critiques of the health insurance systems are directed toward determination of which groups of insured persons have more and which fewer privileges. This type of investigations in many developing countries have shown that insured persons in the urban environments use much more health care than those in the rural environments, first of all because of the higher accessibility of the health organizations and services to the population in the cities. According to some other investigations the poor social layers are in more

favourable situation in spending health insurance funds because they become ill more often and use the health care and services much more, even they contribute less in real quantity of sources. Because of that in the compulsory health insurance systems, which includes the whole population, the principle of equity is much more expressed than in the other types of health insurance (for example: branch-sectoral insurance). In some social health insurance systems, eligibility is based on employment or linked to contributions. This may limit the access of the non-employed population, including elderly and unemployed people and dependants, to health services. As the link between benefits and contributions remains strong, coverage also tends to be limited to curative and medical interventions and few, if any, public health interventions. Because social health insurance relies on a narrow revenue base dependent on the contributions of employed people, it may not generate sufficient revenue, especially in countries with low participation in the formal labor force. An increasing proportion of the workforce is self-employed or in multiple occupations, which also increases the difficulty of collecting social insurance contributions. If social insurance is not mandatory for the entire working population, it can create a perverse incentive for employers. Thus, they may offer (part-time) jobs that pay below the minimum threshold, outsource employment so that contractors are self-employed or create jobs in the shadow or unofficial sector. These practices are common in CEE and FSU countries with newly established social health insurance schemes: employers, faced with an adverse economic climate, have tried to minimize labor costs by evading contributions to social health insurance. A single fund may produce low administration costs, ease regulation and make the risk pool universal. However, subscribers have no choice, and some conservative commentators fear inefficiency and a lack of consumer responsiveness (6,17).

The Role of the Private Sources in Financing of Health Care

The role of the private sector in the area of health care is becoming stronger in developed, but in developing countries, too, observed in general, as well as the private sources in financing of health care as an effect of that. That is a result of the liberalization in regard to the possibilities for establishment and functioning of private health institutions and more favourable conditions that enables the health care professionals to work in the public and the private sector at the same time. A limited privatization is accepted as a principle for all countries, not only because of economic but because of professional-medical reasons, too. Many countries in which the private practice was prohibited or limited, now reintroduce it again in a manner to act equally with the public sector as a part of the health care system as a whole.

There are also countries that have created legislative preconditions for functioning of private ordinations within the public health institutions after working hours. In many countries there are also legislative possibilities that enable private practitioners to have a certain number of hospital beds in the public hospitals for their own patients. In a small number of countries there is an intensive process of privatization with tendency to decrease the influence of the state in the health sector and to preserve it only in the sphere of preventive medicine (public health), and everything else to transfer into the private sector, including the private health insurance. Private health insurance premiums are paid by an individual, shared between the employees and the employer or paid wholly by the employer. Premiums can be: individually risk rated, based on an assessment of the probability of an individual requiring health care; community rated, based on an estimate of the risks across a geographically defined population; or group rated, based on an estimate of the risks across all employees in a single firm. The agents collecting private health insurance premiums can be independent private bodies, such as private for-profit insurance companies (commercial insurers) or private not-for-profit insurance companies and funds. Substitutive insurance is an alternative to statutory insurance and is available to sections of the population who may be excluded from public cover or who are free to opt out of the public system. In Germany and the Netherlands, individuals with high incomes may purchase substitutive health insurance. Where health insurance is supplementary, it may allow quicker access to services or increase the quality of „accommodation" facilities in the public sector. This can result in differential access between those with and those without private insurance. Complementary health insurance offers full or partial cover for services that are excluded or not fully covered by the compulsory health insurance system (6,14).

In some countries are present opposite processes, where the private sources for financing of health care represent a small part in the health care expenditures. In those countries there is a tendency for achieving a balance in which the state as well as the compulsory health insurance and the private sources will have an equal role in financing of health care. In many countries, the transfer of the health care expenditures onto the private sources most often is connected with a tendency for stopping of its increasing, in other words to bring the health care expenditures down within the real possibilities related to the increase of the gross national income.

Out-of-pocket payments include all costs paid directly by the consumer, including direct payments, formal cost sharing and informal payments. Direct payments are for services not covered by any form of insurance

(the purely private purchase of uncovered services). Other payments are for services included in the benefit package but not fully covered (e.g. formal cost-sharing) or for services that should be fully funded from pooled revenue but additional payment is demanded (e.g. informal payments in CEE and FSU countries) (6,19).

However, in regard to this approach arise many problems among which especially important is the problem of providing equity in health care consumption and its accessibility to some population groups, which have no possibility to pay for health care services out of pocket or to purchase insurance policy from the private health insurance agencies. Investigations about the efficiency and quality of the health care didn't show advantages in the non-profit institutions that as a rule provide services under lower prices, although there is a higher administrative efficiency. Therefore, the privatization and de-privatization of the sources for financing of health care present two opposite processes that run simultaneously in various countries. The goal of both processes is to achieve a balance between health care expenditures and the real financial possibilities. In spite of all there shouldn't be disregard the fact that health is one of the basic human rights, and the equity in providing health care is one of the indicators for the level of respecting human rights. In developed countries the participation of the private sources for financing of health care/ expenditures goes from 14.8% in Norway and 17.9% in Denmark to near 60% in USA, and in the SEE countries from 15.4% in Croatia and 15.5% in Macedonia to 49.0% in Serbia and Montenegro (Table 2). This type of differences in financing of health care, as well in regard to the real possibilities for increasing of the sources for health care in developing countries, clearly show that financing in health care is a very intricate problem.

External Sources for Financing of Health Care

The foreign aid, as an external financing source for health sector in many poor countries, by the international health and other organizations and from the other countries, as a manner of bilateral cooperation, usually is too small to give bigger effects in regard to the financing of health care. This help, as a rule, is directed to certain developmental projects and specific programmatic objectives in developing countries with measurable outcomes (vaccination, disease elimination, safe childbirth). This help usually mitigates the situation, but doesn't solve the problems in a long run. Care must be taken to ensure that external funding is additional to, and, not a substitute for, domestic financing, but also that financing which flows from outside sources does not lead to (further) fragmentation of the national health system (3).

Other external sources, such as donations from non-governmental organizations, transfers from donor agencies and loans from WHO and other UN agencies, The World Bank and other international banks and funds, also contribute significantly in some countries, especially low- and middle-income countries (6). Multilateral development banks are coming under increasing pressure to finance multi-country initiatives directly, rather than through conventional country-based grants or loans (20).

EXERCISE: Financing of Health Care

Task: Seminar Paper

Students should use additional recommended readings in order to increase their knowledge and understanding of health care financing. As output, students should write a seminar paper, stressing the importance of different sources of financing health care, giving the reasons for permanent shortage of resources, discussing percentage of GDP input and overall, make comparison between global and their own country ways of health care financing.

In addition, students should be encouraged to make an investigation regarding the financing of health care in their own region (local, municipality, county/regional within the country, as well as at country level) and compare the facts with those for neighbouring countries (SEE) and widely at international level. They should be asked to search the internet in order to find the data and write their seminar papers not repeating the data from the module itself but to interpret their own findings in context of the facts from module. Moreover, they should be able to place the data collected in field study into the context of the module, they need to see how the data feet together. Not only data but also regulations are different and important and all the information about the kinds of compulsory (national) and private (voluntary) insurance could be find, for each SEE country, on the Health Insurance Fund web-sites (for example: for Croatia visit http://www.hzzo-net.hr and for Slovenia visit http://www.zzzs.si/). Public health lecturers in each SEE country should be qualified to direct the students to data sources in their countries (provide respective web-sites in SEE countries and not only at country level but also at local - municipal, county, regional level).

Students ought to be able to investigate the ways in which health care is financed and how revenues are pooled (much more could be find at local level). Students must be able to find very new data about GDP and health expenditures, and to calculate percentage of GDP spent on health care. To manipulate data is important not because of making calculations but in order to get a perception of data, data sources and the students ought to know (or they need to be instructed and trained) where to find the information on regional, national and international level. Students have to know where to look for example for current GDP - it is usually National Statistical Office web-site (in Macedonia www.stat.gov.mk; in Croatia www.dzs.hr) or printed publications as Statistical Yearbooks.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Payment Methods and Regulation of Providers**
Module: 2.5	**ECTS (suggested): 0.25**
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Keywords	resource allocation, health payments; regulation of providers; budgeting; fee-for-service; capitation; case-base payment, diagnosis related groups, resource allocation reform, Europe, South Eastern; health planning
Learning objectives	At the end of this module students and health professionals should be able to identify: • resource allocation mechanisms and payment methods for regulation of providers, • methods of payment for primary health care providers, • payment and regulation of hospitals and other health facilities.
Abstract	Allocation mechanisms and provider payment methods refers to the ways in which money are distributed from a source of funds to an individual provider or to a health care facility. There are three main methods for payment for doctor's services: fee-for-service, capitation and salary payment; and four basic methods for payment and regulation of hospitals and other health facilities: global budgeting, line item budgeting, per diem and case-based payment (DRGs).Each method for payment to providers has its own specificities, strengths and weaknesses, and each may be appropriate alone or in combination with other, which depends on various circumstances and environment.
Teaching methods	Teaching method will include combination of introductory lectures, group work and discussion followed by group report presentations and overall discussion, as well as practical individual work assignment.
Specific recommendations for teacher	This module to be organized within 0.25 ECTS credit. Beside supervised work, students, as a practical work assignment, should collect some specific indicators (HFA Database and other sources) and to prepare a seminar paper about the allocation mechanisms and payment methods to providers in their respective countries.
Assessment of students	The final mark should be derived from assessment of the theoretical knowledge (oral exam), contribution to the group work and final discussion, and quality of the seminar paper.

PAYMENT METHODS AND REGULATION OF PROVIDERS

Dončo Donev, Luka Kovačić

Resource allocation and provider payment methods in the health care system can have impact on provider's behavior, and therefore on the achievement of the objectives of the health care system (efficiency, equity, cost containment). The allocation of financial resources should reflect the outcomes achieved, and include incentives for improving the quality of care (1).

Provider payment method refers to the way in which money are distributed from a source of funds, such as the government, an insurance company or other payor (all also referred to as fund-holders), to a health care facility (hospital, PHC centre etc.) or to an individual provider (physician, nurse etc.). Each provider payment method carries a set of incentives that encourage providers to behave in specific ways in terms of types, amounts, and quality of services they offer (2). It means that the payment system should be directed to provide the right incentives (or disincentives) in order to promote (or discourage) certain types of behaviour, and therefore to improve the efficiency and the quality of health services and to provide equitable financial access to care with the use of existing resources effectively.

It is not easy to develop payment system and to provide right incentives (or disincentives) and to measure related performance. In general, health outcomes are problematic to measure, and may not be directly attributable to the performance of the individual health care provider, but rather to their team or other determinants of health status. It is also difficult to measure the behavioural response of providers to changes in payment systems (3).

Provider payment reform is often linked to government efforts to improve the efficacy of the health care system through various means, among others: 1) decentralizing the management of the health system; 2) separating health financing functions from the institution providing care; 3) contracting for public health services with private sector providers and non-governmental organizations; 4) developing or reforming public or private health insurance to expand coverage of the population; 5) promoting primary and preventive care over reliance on expensive curative and hospital-based care; and 6) improving hospital management and quality of care (2).

Incentives and disincentives for efficient care include how providers and facilities are paid, and how services are organized.

Resource allocation according to needs

The evidence suggests that a strategic approach to resource allocation and priority-setting is needed, in order to coordinate decision-making at different levels, and this should start with a discussion and a decision on the values and principles to be applied when determining need and selecting priorities. A debate (involving government, health service and care providers, the public and patients) on the ethical, political and social questions that need to be addressed must precede any decision on the rationing of resources. The term „funding" is used to describe allocating the revenues, that have been already raised, to health care organizations and to alternative activities within the health care sector, usually through budgets or payments to providers, public not-for-profit and for-profit institutions and firms (3). Any rationing of access to necessary services should be preceded by a thorough scrutiny of the overall organization and of the cost and effectiveness of the services and care provided.

Needs-based resource allocation formulae have been introduced into some countries in the western part of Europe and are now being developed in some countries in the eastern part, in particular regarding the geographical allocation of resources and services.

Contracting is a mechanism that offers an alternative to traditional models of resource allocation, binding third-party payers and providers to explicit commitments and generating the economic motivation to meet these commitments. Four major reasons have been put forward for introducing contractual relationships into tax-based systems, based on the long experience of health insurance systems: 1) to encourage decentralization; 2) to improve the performance of providers; 3) to improve the planning of health service and care development; and 4) to improve management (2).

Contracts can support equity if, through needs assessment, resources are allocated as a priority explicitly to disadvantaged population groups. The role of governments should be to ensure equity, in order to avoid over-emphasizing profitable, rather than effective, services.

Basic Arrangements for Resource Allocation

There are three different basic arrangements by which to distribute revenue to health care providers: 1) the reimbursement model; 2) the contract model; and 3) the vertically integrated model. Combined, there are thus at least seven major payment methods or alternative ways for payment to health care providers (4).

Payment for Primary Health Care (PHC) Providers

Payment system for PHC providers should contribute to achievement of the best possible health outcomes. An optimum payment system for PHC providers should also ensure the following: financial management of the different components of PHC within a country's total health care expenditure; a balanced package of health promotion, disease prevention, treatment, and rehabilitative services; a free choice of health care provider for all individuals; a structure of fair rewards for practitioners which recognizes workload and professional merit; acceptance of health care providers' responsibility for and accountability to the population and responsiveness to the needs of the community, the family and the individual; promotion of close collaboration among health care providers; and a democratic system of decision-making. Finally, the system should allow purposeful, flexible management aimed at achieving continuous quality development and greater cost-effectiveness (1).

The main methods of remuneration or paying doctors and other health care professionals for their labour at PHC level are: fee-for service, capitation and salary, or some combination of these methods. Each of them has its historical roots, advantages and disadvantages, and the incentives they create for providers, payors and consumers (1,5,6).

1. Fee-for-service is payment for each unit of service or intervention provided (visit to doctors office for counselling, testing or treatment prescription, intervention or surgical procedure), which can be paid directly by the patient (user charges) or by the third party payer (insurer or government). Fee-for-service is a common method of payment for doctor's services in many countries, such as Germany, USA, Canada and other countries (5,8).

In most countries fee-for-service payment is regulated by a prospectively fixed fee schedule, negotiated by the fund-holders and the provider's representative.

Because of incomplete information and so called *information asymmetry* as a result of superior knowledge of the health care providers, doctor helps

the patient to make choices and patient may be unable to judge the performance of the doctor, before or even after the intervention. Disadvantage of this method of payment is that provider might neglect codes of medical ethics in protecting the consumer's best interests and to influence patient's demand for health care, especially for more expensive kinds of care, including surgery, for the providers' own self-interest (income). This creates potential incentives for inappropriate services and over-treatment (over-servicing), in excess of real needs, especially when the patient is fully covered by health insurance and when the specific actions undertaken by the physician cannot be monitored, measured, or well understood. That is known as *supplier induced demands*. Fee-for-service and other retrospective forms of payment result in an input-intensive, gold-plated form of service that often extensively expends resources. On the other side, fee-for-service method of payment discourages provision of care not defined as a service in the fee schedule (because a „covered" service is the unit of payment) (3,6,7).

Some fund-holders introduce participation of the user in the cost of service (user fees or charges), which is called *co-payment*. In fact, co-payment is the portion of covered health care cost for which the person insured has the responsibility to pay, usually based on a fixed percentage. The method of co-payment is a regulative mechanism for rationing the health care, in order to prevent consumers to seek unnecessary care, as well as a source for additional funds for health care (financial input). Co-payment often is an issue for political debate (hot potato) because the opponents argue that user fees affect the poorer strata of the population disproportionately and discourage preventive care services/activities (3,5).

Case-based payment to physicians at primary level is not common, but might be popular prospective form of payment for specialty physicians and for hospital outpatient services builds on the episode-of-illness payment methodology. That is payment per case-rates or episode of illness i.e. for obstetrical care as a complete service including prenatal care and delivery, or certain surgical, cardiological etc. package of care over an illness or period of care, usually on a monthly basis (fee for the preoperative/pre-intervention workup, the procedure itself, and postoperative monitoring) (5,6).

2. Capitation for doctor's services is advanced payment by a fixed sum of money for the persons registered for care with the physician for a defined period of time. It means that capitation is prepayment for services on per member pre month (pre year) basis by some amount of money every month (year) for a member regardless of whether that member receives services and regardless of how expensive those services are. This method of payment pro-

vides good cash flow, less lost-costs and applied and good case management, and can be for a comprehensive health services or for general practitioner services. In the UK, for example, around 60% of general practitioners' income is derived from an annual fee paid by the National Health Service (NHS) for each patient on a GP's list. The costs might be predicted because the fee depends on the age and sex of the patient (age/sex adjustment of physician capitation rates), and the level of the deprivation of the area. Capitation payment put risk on provider and has the advantage for utilization control because it does not contain incentives for provider to over-treat the patient. There is some incentive for the doctor to maintain quality of care in order to attract and retain patients even this is limited by information problems. Providers are also motivated to undertake health promotion and preventive care as this may reduce costs later in the health care process. In UK recently were introduced incentive fees for full immunization and screening programs in order to improve the performance in these areas. Main weaknesses might be to adjust capitation payment adequately to reflect the diversity in disease severity among patients, which leads to incentives for *adverse selection* and patient dumping, difficulties to determine break-even point (volume), avoiding high-risk and high-cost patients or reducing treatment for them, inappropriate under-utilization (narrow scope practice), and misunderstanding of the meaning of capitation by provider. There may be incentives to under-treat (subject to keeping patients happy and therefore retaining them), and to shift costs to elsewhere in the health care system (for example from primary to secondary care). The interaction among payment mechanisms (capitation at primary level and fee-for-service payment at secondary level) might provide incentive for over-referral and convert primary care physicians into triage agents (3,5,6).

3. Salary payment for doctors and other health workers is the final payment mechanism in form of salary where doctors are paid to provide a certain amount of their time to carry out specified responsibilities for an organization and to perform a defined role, usually being available to provide needed health care services at specified times (and places). The salary level is likely to be negotiated between the professional associations (or Health Workers Trade Unions) and fund-holders (Government, insurance company or managed care organization), and will vary according to the age, experience, grades or levels of education and responsibilities of the health workers. The advantage for providers is predictability and stability of income, and it gives less incentive to over-treat, but may contain incentives to under-treat or shift costs from primary to higher levels. In addition, a hospital doctor paid a salary may choose, with a given availability of beds, to have a longer average length of stay (reducing overall workload) rather than faster throughput (which would increase work

without increasing income. In general, salary payment undermines productivity, condones on-the-job leisure and fosters a bureaucratic mentality. It means that provider might consider that every procedure is someone else's problem because payment is based on minimally meeting responsibilities (to retain one's position) (3,6,7). That is why salary payment is often combined with incentive payments for additional services.

Wage is a payment mechanism whereby a provider receives a pre-specified sum of money for each hour of work they provide to an organization. It can be used only for remuneration. Although the wage is normally pre-set, the total payments depend on the number of hours worked. The incentives are similar to salary, except that payment is even more closely tied to time spent at the workplace (7).

The type of payment system depends of the financing of the health care system and the public-private mix of financing, as well as of the provision and the desired activity levels of physicians and other health workers. Payment systems are therefore likely to involve a mix of methods. Increasingly mixed systems of payment are emerging, with capitation as a predominant method at the primary health care level (5).

Payment and Regulation of Hospitals and Other Health Facilities

There are four main mechanisms for paying hospitals and each of them create different incentives for the service provider and different effects in relation to the objectives of equity, quality of care, efficiency and cost control / cost containment (3,5).

It is not easy to measure efficiency and outcomes of health care in the hospital sector. Efficiency should be measured through input (resources used in delivering care), process (method of delivering care, day cases and inpatient cases, length of stay etc.), and outcome indicators (the result of care – whether or not it has been of benefit to the patient). Measuring outcomes of health care is often attempted to estimate process and hospital activity through some indicators (average length of stay, bed occupancy and turnover rate), which have uncertain relationships with cost, patient outcomes and efficiency.

If activity measures are used in payment systems for providers, they should be good proxies for outcome. Rewarding turnover of patients may give incentives for discharging patients „quicker but sicker". Nevertheless, too many indicators can create confusion and dilute incentives. Prospective budgeting has evident merits: it limits expenditure to funding a given level of ser-

vice provision that is determined in advance for a defined period. A prospective budgeting system can be recommended if it incorporates the use of case-mix controls and output measures. Classification systems based on diagnosis or on the characteristics of the patients can be used to better analyse cost structures, evaluate hospital performance and quality of care, and make comparisons between hospitals in terms of costs and quality, as well as in negotiating contracts between hospitals and those purchasing services. Alternatively, a volume-based approach can be made to work by using prospective pricing and contracting or planning agreements for agreed levels of service provision. In this way, hospitals can be obligated to achieve specific objectives of cost control and effective resource utilization, stimulating them to review and adjust their current organization, staffing levels and internal resource allocation (1,3).

4. Global budgeting is defined as a total payment, almost always prospectively, fixed in advance as a constraint on providers to limit the price and the quantity of service, to be provided in a specified period of time. Global budgets are difficult to amend over the budget period, but some end-of-year adjustments may be allowed. It means that the global budget becomes a financial plan (and resource constraint) within which the hospital or other health facility has to operate. Resource allocation decisions are made among the many diverse, but interdependent activities and programs of the health care providers. The global or operating budget is always for a specified period, usually one year (calendar or fiscal), although it might be a biennial or a semi-annual budget (5,7,8).

Various formulas can be used for establishing a global budget for a hospital or other health facility. Because global budgets do not contain incentives for good performance, it is important to specify either the volume of activity or the price of each of the services included within the budget. In order to prevent the provider to minimize the number of patients treated and the amount of care given to each patient, since the money received will be the same, it is necessary to determine the scope of services included, patients eligible for treatment and methods of care delivery (i.e. inpatient, outpatient, day case, diagnostic testing). The global budget may reflect the anticipated volume of activity and services derived from the utilization rates for the previous year or to be based on per capita rates with various adjustments (age, sex). Global budgeting usually relates the level of resources provided (the budget) to the level of activity to be undertaken, and is therefore focused on inputs and not on outputs. Because the determination of the process of delivery of care is left to the provider, who tends to maximize profits (by undertaking the required activity for easy cases as cheaply as possible, with potential for cost shifting and

the quality to be compromised), additional regulation is needed for quality to be maintained and clear quality standards to be specified by global budgeting agreements / contracts between purchaser and provider. The global budget can include also some capital costs if necessary to built / broaden or renovate the capacities or purchase some capital / costly equipment (3,5,9).

The main advantage of a global budget for cost-containment is that the cost paid by the fund-holder / purchaser is fixed, and therefore the financial risk is transferred to the provider, assuming that there are „good" and well-constructed activity targets. The advantage for local managers is flexibility about the use of resources and the methods of undertaking care within the budget limits. Disadvantage of global budgets is that it provides incentives to skim on quality of care, engage in risk-selection, and provides few incentives to improve micro-efficiency despite helping contain costs. There is no control of quality inherent in global budget framework. Furthermore, global budgets provide incentives for hospitals to avoid complicated cases and seek out simple ones. In order to address these problems, activity targets including expected case-mix is important (3,7).

5. Line Item Budgeting is a variant of global budgeting with subdivision of the budget allocated according to specific input categories of resources or functions (salaries, medicines, equipment, food, maintenance etc.). This method of hospital budgeting process and contracting methodology is generally similar to that for global budgeting, but more complex and more difficult to monitor with much more details, since each item of expenditure might be subject to an individual contract and possibly a service specification (3,5,7).

Initial step of the budgeting process is gathering retrospective data and financial information including all expenses and revenues, units of services (case mix index), staffing information including a breakdown by job code and type of working day-time hours (e.g. base staffing, overtime, non-productive), and current year projections with detailed analysis and evaluation. The second step relate to determining the units of services and expected changes in number of patients, which is driving force for changes in both revenues and certain types of expenses. Special attention should be paid to the inpatient routine units of services – patient days, discharges (or admissions), adjustments for intensity of care, as well as to ancillary units of services. The third step of the budgeting process relates to staffing and payroll, which is the most important, high time-consuming and the single largest portion of the budget. Special attention should be paid to the base staffing and payroll, overtime, other budgeted hours, contract codes, pay increases, occurred vs. paid staffing and payroll, and productive vs. non-productive time. The next separate category of the budget are

the fringe benefits (social security, pension and retirement, health insurance, disability, unemployment and life insurance, tuition reimbursement etc.). Special category of the budget is non-salary fixed and variable expenses (medical/surgical suppliers, drugs and pharmaceuticals, general suppliers, professional and physician fees, insurance, interest and depreciation, purchased services, travel costs, and utilities). And, the last category of the budget are revenues and allowances: gross and net patient revenue, rate charges, allowances and deductions from revenue, contractual allowances and other operating and non-operating revenue (3,5,7).

Line item budgeting, in general, offers similar incentives as global budgeting, with an exception with limited or no possibility of reallocation of resources between cost units/ categories. That might be a limitation for hospitals for efficient methods of service delivery because of few incentives for efficient production of health services, and little flexibility of managers (2). Advanced budgeting, as an alternative method of variance reporting and adjustment of revenues and expenses based on increases or decreases in unit services, is more flexible budgeting. Reports on advanced budgeting cover flexible budget as compared to actual and fixed (static) budget. Main strengths of advanced budgeting are that budget can be adjusted in order to reflect actual activity level, it is easier to obtain meaningful variance analysis, and to generate a more enthusiastic acceptance by department managers.

In line item budgeting the recurrent (operational) costs should be separated from capital costs, too.

6. Per diem or flat rate per patient-day is retrospective method for payment of hospital activity. This method, as well as other retrospective methods of payment (fee-for-service or per procedure, course of treatment, per admission or cost-per-case based payment) encourages hospitals to maximize income by maximizing the volume of activity. Per diem method gives incentives to hospitals to increase the number of admissions to hospital for diagnostic tests or care that could be provided in alternative and less costly ways (ambulatory or day care services), to hospitalise and provide prolonged care for a relatively well patient and to avoid or refer the sicker patient to other hospital/university clinic (cost shifting), or to prolong length of stay, particularly as the cost per day of care declines as length of stay increases (3,7).

Fee-for-service payment for each service, procedure or course of treatment in hospitals, as well as cost-per-case based payment (per admission), favours unnecessary marginal care, long lengths of stay, high admission rates, and provision of duplicative or unnecessary services (5).

Per-diem payment and other retrospective methods of payment provides no direct incentives to ensure quality of care, efficiency and cost-containment.

7. Diagnosis Related Groups (DRGs) is prospective method for payment of hospitals by predefined charge per case, within the payment rates for each type of case being determined in advance. Patients/diagnoses should be categorized into disease categories, so called Diagnosis Related Groups, in order to facilitate billing and reimbursement by estimate cost of individual treatment. Reimbursement rates are negotiated between purchaser and provider and they are set to reflect the expected average cost for particular DRG. Reimbursement payments are divided into four major components: 1. room and board, 2. professional service, 3. diagnostic tests and special therapies, and 4. consumables and drugs (5,7).

The number of DRGs vary from 470, or even more, in USA (introduced in early 1980s for Medicare Program for elderly) to around 20 diagnostic groups in Chile, which greatly simplifies the classification process and accounting around 60 percent of inpatient care expenditures. The remaining 40 percent of procedures are covered under management contracts and prospective budgets. During 1990s this method of prospective payment to hospitals was introduced in Norway (1991), Sweden and Ireland (1992), Hungary (1987-1993), United Kingdom (1993), Italy (1994), Germany, Belgium and Spain (1995), Czech Republic (1996), and than in some other countries (Canada, Denmark, Australia and Philippines). Anyhow, for implementation of this method of payment should be available a reliable patient information system in order to record diagnoses, procedures, and important items of resource use such as diagnostic testing and length of stay (3,5).

DRG payment method has advantages of reducing incentives to overtreat, permitting cost containment and generating data and information. There are also some limitations and adverse effects in using DRGs payment method: 1) incomplete coverage of DRGs (they do not cover psychiatry, outpatients or physician fees for the uncovered items); 2) promoting technological changes (day case surgery), which might be beneficial but in many cases are with unproven efficiency; 3) sticky prices, once fixed, are difficult to change, regardless of advances in technology and falling unit costs, and therefore offer providers increasing profits over time; 4) DRG creep - activity of classifying patients into the most remunerative DRGs possible through undertaking additional diagnostic tests and identifying additional health defects and problems; 5) data requirements can limit the use of DRGs in countries with insufficiently developed health information system, particularly in developing countries (3,7).

The main objective of DRGs prospective payment is to control costs by motivating providers to deliver care as cheaply as possible. Hospitals have incentives to improve performance and to reduce expenditure by reducing length of stay, cutting out unnecessary tests and avoiding duplication. The tendency of hospitals to reduce costs sometimes may compromise the quality of services provided and health outcomes to be worsened, i.e. earlier discharge could lead to higher rates of mortality, morbidity and readmission to hospital – a „*quicker – sicker*" problem. DRGs with fixed prices across all providers stimulate competition based on non-price factors, notably on the quality of services, short waiting times and the quality of he hospital environment. Quality competition is likely for profitable patients, i.e. those whose treatment is expected to cost less than the DRG reimbursement level. *Perverse incentives* for providers appear when case-mix selection is allowed and hospitals may select the patients they treat. It means that hospitals have incentive to avoid and not to treat patients who are older, sicker or more likely to have complications because the treatment costs for them will probably be in excess of the DRG average (*adverse selection*). Such hospitals would prefer to treat simple cases and to minimize costs and maximize profit (*cream-skim* phenomenon) (3,5,7).

Case mix selection can occur if providers are allowed to select the patients they treat. This is important because even within DRGs, some patients may be older, sicker, or more likely to have a treatment cost in excess of the DRG average. If payments are made on the basis of DRG average cost, profit-maximizing hospitals have an incentive not to treat these patients. Such hospitals would prefer to cream-skim treating simple cases, minimizing costs and retaining any excess of income over expenditure. To avoid cream skimming there must be adequate case-mix adjustment within DRGs, which can be complex. Case-mix can be measured based on patient's diagnoses or the severity of their illnesses, the utilization of services, and the characteristics of a hospital. Case-mix influences the average length of stay, cost, and scope of services provided by hospital (3,7).

Conclusion

There are three main methods for paying doctors: fee for service, capitation and salary, and four main methods for paying hospitals: global budget, line-item budget, per diem and case based payment (DRGs). The practice shows that there is no ideal method for payment of providers. Resource allocation decisions should be made among the many diverse, but interdependent activities and programs of the health care providers, and because of that the reimbursement or budgeting is a complex process, usually involving input

from many sources. Anyhow, the creation and maintaining of a detailed operating budget is an important component of cost control. It means that each method for payment to providers has strengths and weaknesses, and each may be appropriate alone or in combination with other, which depends on various circumstances and environment. Nevertheless, many health care systems have moved away from fee-for-service as predominant payment. Mixed payment systems, with a prospective component based on capitation together with fee-for-service for selected items, seem to be more successful in controlling costs at the macro level, while ensuring both patient and provider satisfaction and achieving efficiency and quality at the micro level. The tools available for management include the use of different incentives to influence patterns of care (e.g. to offer more preventive services) and ensure equitable distribution of primary care providers throughout the country (1,9,10,11,12).

Reimbursement of the hospital providers is complex, and depends on specialization or complexity of hospital services. For example, to use a global budget might be appropriate for well-defined care, such as maternal services. But, when services are more complex and variable, such as oncology or trauma, payment through global budget might be less appropriate. Choice of payment method for health care providers is a long, complex and detailed process including appropriate devising of incentives and contract specifications in order to achieve health care objectives (efficiency, quality, equity and cost-containment, as well as consumer satisfaction). Difficulties in selection of the method for reimbursement of providers are springing out from the specific subject and product - thousand of different illnesses and treatments, and, for the same illness, treatment patterns can be substantially different for different physicians and providers. From the other side, the quality of health care services and outcomes is very difficult to quantify and measure. Projection of net revenue is difficult to determine because of different payors and payment methods, and because of rapidly changing of payment methods. When a third party payor (insurance agency) contracts with providers to pay for the care of covered patients by health insurance, it is recommended for each of the payment methods to be accompanied by some payment out of pocket of the patient (1-3,5,9).

Each payment method should be supported by legal framework and management information system, effective referral system, and financial and management autonomy of the providers.

The main characteristics and differences, as well as the distribution of the financial risk between payors / purchasers and providers, are summarized in the attached Table 1 (2,3,6,7).

Table 1. Seven Major Payment Methods: Advantages and Disadvantages

Payment method	**Unit of payment**	**Prospective or retrospective**	**Description**
1. Fee-for-service	Per unit of service or intervention provided	Retrospective	Separate fees for different service item e.g. medicines, consultation, tests, surgical procedures
2. Capitation	Per person per year (month)	Prospective	A payment made by fix sum of money directly to health care provider for each individual enrolled with that provider for a defined period of time. The payment covers the costs of a defined package of services for a specified period of time. In some instances, the provider may then purchase services which it cannot (or choose not to) provide itself from other providers.
3. Salary	Payment to providers, usually on a monthly basis	Retrospective	Individual payment to doctor and other health worker, in accordance with the age/experience, grade/level of education and responsibilities of the providers, for their performance for defined period of time (week, month).
4. Global Budget	Health facility: hospital, clinic, health centre	Prospective	Total payment fixed in advance to cover a specified period of time. Some end-of-year adjustments may be allowed. Various formulas can be used: historical trends, per capita rates with various adjustments (age, sex), utilization rates for the previous year/s.
5. Line item Budget	Functional budget categories, usually on an annual basis	Either	Budget is allocated according to specific input categories of resources or functions, usually on an annual basis. Budget categories include: salaries, medicines, equipment, food, overhead, administration.
6. Per diem	Per day for different hospital departments	Retrospective	An aggregate payment covering all expenses incurred during one inpatient day.
7. Case-based payment (DRGs)	Per case or episode	Prospective	A fixed payment covering all services for a specified case or illness. Patient classification systems (such as Diagnosis Related Groups - DRGs) group patients according to diagnoses and major procedures performed. Most frequently applied to inpatient services, although outpatient groups are being developed.

Payment method	**Method efficiency**	**Quality and equity**	**Management and Information systems**	**Financial risk**
1. Fee-for-service	+ Flexibility in resource use - Tendency for provider to increase number of services in order to increase revenue (supplier induced demands)	+ Payment is directly related to intensity of service required - There is a tendency to over-service or provide unnecessary interventions.	Providers must record and bill for each medical service transaction.	Provider = LOW Payer = HIGH
2. Capitation	+ Flexibility in resource use with good cash flow and less lost-costs + The more services included in the package the less the scope for cost shifting + Resources closely linked to size of population served and their health needs + Good case management	- Providers may sacrifice quality in order to contain costs - Rationing may occur if capitation is too low (narrow scope practice) - May encourage providers to enroll healthier patients (adverse selection) - Patient choice of provider is generally restricted + Adjusters in capitation formula can adjust payment to special population groups by age/sex	Management system required to ensure that each beneficiary registers with one provider and primarily uses that provider. Utilization management and quality assurance programs are essential to prevent under-servicing. If payment covers primary and secondary services, providers at different levels of the system must establish contractual links with each other in order to prevent over-referral.	Provider = HIGH Payer = LOW
3. Salary	- Little flexibility in resource use - Usually not linked to performance indicators (e.g. volume, quality) - Gives incentives to under-treat and undermined productivity	+ Payment is fixed and stable - No incentives for physicians to improve quality of care and scope of services (gatekeepers) - Traffic-policeman role with tendency to over-referral and shift costs	Relatively simple	Provider = LOW Payer = LOW
4. Global Budget	+ Flexibility in resource use - Spending set artificially rather than through market forces - Not always linked to performance indicators (e.g. volume, quality, case-mix), low micro-efficiency	- Rationing may occur if budget is too low - If rationing occurs more complex cases may be referred elsewhere	Requires ability to track efficiency and effectiveness of resource use in different departments, and mechanisms to switch resources to most effective uses.	Provider = HIGH Payer = LOW

	- Cost-shifting possible if global budget covers limited services; one provider may refer patient to another who is outside purview of global budget to minimize expenditures under global budget	+ Case-mix adjustments in global formulas link budget amounts to complexity of cases; other adjustors may be used to adjust payment for special population groups.		
5. Line item Budget	- Little flexibility in resource use - Tendency to spend entire budget even if unnecessary, to ensure that level of budget support is maintained	- Rationing may occur if budget is too low - More complex cases may be avoided or referred elsewhere	More complex and more difficult to monitor with much more details	Provider = LOW Payer = LOW
6. Per diem	+ Flexibility in resource use - Tendency for hospitals to increase admissions and length of stay in order to increase revenue	+ Per diem rates allow longer stays for more complex cases - Prolonged care for relatively well cases- Avoid or refer the sicker patientss	Need to track inpatient days by department and ensure costs are covered.	Provider = LOW Payer = HIGH
7. Case-based payment (DRGs)	+ Flexibility in resource use - Tendency for hospitals to increase cases (by increasing admissions or double-counting admissions) + No incentives to over-treat + Permitting cost-containment	+ Case-based payment links payment directly to the complexity of cases + Generating data and information- Shortening length of stay by earlier discharging of patients (quicker-sicker)- Adverse selection and „cream-skim"	Providers need reliable patient information system and ability to record and bill by defined case, which generally entails collecting a large volume of relevant information on patient characteristics, diagnoses and procedures.	Provider = MODERATE Payer = MO-DERATE

EXERCISE: Financing of Health Care and Regulation of Providers

Task: Seminar Paper. Students should use additional recommended readings in order to increase their knowledge and understanding of allocation mechanisms and payment methods for regulation of providers. As output, students should write a seminar paper, stressing the importance of different payment methods for regulation of providers.

Students ought to be able to investigate the ways in which revenues are pooled and how they are distributed to health providers (much more could be find at local level).

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Case Study: The Current Health Insurance System in the Republic of Macedonia**
Module: 2.6	**ECTS (suggested): 0.25**
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Keywords	Health care; health expenditures; health insurance; health payments; health care costs; resource allocation reform; health plan implementation; Macedonia
Learning objectives	At the end of this module case study, students would become familiar with the Health Insurance System in Macedonia.
Abstract	The current Health Insurance System in Macedonia was introduced by the Health Insurance Law, which was adopted in 2000. According to this Law, health insurance was established as an obligatory and voluntary insurance for certain kinds of health care. This case study gives an insight to the specificities and practice of both mentioned types of insurance in Macedonia, to the scope of the insured persons and their rights and obligations, the way of realization of health insurance in practice. Calculation and payment of the contributions and the other sources of revenues, co-payments, autonomy and scope of activities of the Health Insurance Fund, as well as health care and health insurance reforms within the last 12 years.
Teaching methods	Teaching methods will consist of combination of an introductory lecture, group work followed by group reports and overall discussion, practical work.
Specific recommendations for teacher	This module to be organized within 0.25 ECTS credit. Beside supervised work, students should collect some specific indicators (HFA Database and other sources) and readings about the Health Insurance System in their respective countries in order to prepare a seminar paper as practical work.
Assessment of students	The final mark should be derived from assessment of the theoretical knowledge, contribution to the group work and final discussion, and quality of the seminar paper.

CASE STUDY: THE CURRENT HEALTH INSURANCE SYSTEM IN THE REPUBLIC OF MACEDONIA

Dončo Donev

Health insurance, as one of the most significant civilization gains of the contemporary world, presents a legal normative and regulatory organized mechanism for acquiring funds on different bases, in order to provide prompt quality and efficient prevention and protection of people's health.

The current Health Insurance System in the Republic of Macedonia was introduced by the Health Insurance Law (1), which was adopted in March 2000, and modified and supplemented by the amendments in 2000 (2) and 2001 (3). The Health Insurance Law was empowered on April 7th, 2000, and at the same time the articles of the 1991 Health Protection Law (4) related to the health insurance were put out of power. In fact, the current health insurance system in the Republic of Macedonia is somehow continuation of the previous one (5), with some modifications and new way of regulation of the relationships within the health insurance related to the obligatory and voluntary insurance, the scope of the insured persons and their tights and obligations, the way of calculating and payment of the contributions and the other sources of revenues for health insurance, user participation in health care expenses, as well as the scope of activities and responsibilities of the Health Insurance Fund that was established as an independent institution outside of the Ministry of Health.

There are two types of health insurance according to the Law on Health Insurance: obligatory and voluntary insurance for some kinds of health care.

Obligatory health insurance was established for all citizens of the Republic of Macedonia in order to provide social and health security and to realize certain rights in case of disease or injury and other rights from health care established by Health Insurance Law. Obligatory health insurance is based on the principles of obligation and universal coverage, solidarity, equity and effective usage of the financial resources in accordance with the Law. It means that when necessary, each insured person can use the health care and the rights from health insurance, in an unlimited amount for basic health care rights, covered by the obligatory health insurance. On the other side, there is an obliga-

tion to all employees and other bearers of insurance for continuous payment of contributions for health insurance. The contribution rate is the same for all employees, regardless, of the level of salary or income, or the frequency and amount of the health services use on the account of the health insurance funds. The principles of solidarity and equity are compulsory (1,4,5,6).

Some special risks and services, which are not covered by the obligatory health insurance, should be provided to certain groups of workers by their employers. It includes preventive and screening measures and use of health care in case of injury at work and occupational diseases of the insured on the employment basis, due to the increased risk at work. It also applies to the insured professional sport persons, drivers, pilots and other aircraft crew etc.

Voluntary health insurance was introduced for the health services that were not covered by the obligatory health insurance. It covers use of some specific health care services, as well as services at a higher level of standard or comfort than those offered by the obligatory health insurance, in accordance with the agreements and norms set by the agency / company that provide voluntary insurance. Voluntary health insurance is an additional insurance, allowed only for the insured within the obligatory health insurance. However, due to the lack of interest shown by the citizens for realization of the voluntary health insurance rights, as well as due to the wide range of obligatory health insurance rights, voluntary health insurance has not yet been implemented in practice.

Modalities of becoming an Insured through Obligatory Health Insurance

2000 Health Insurance Law promotes various modalities for a person to become the member of the obligatory health insurance offered by the Health Insurance Fund (HIF). Almost all citizens (more than 80% of the total population) of the Republic of Macedonia are insured by the obligatory health insurance system, in various modalities: (a) on the basis of their employment - employed individuals (workers), individuals working in the private sector, and individuals performing agrarian activity (farmers); (b) on the basis of their retirement rights - retirement, disability and family pensions, as well as pensions and disability rents from foreign insurance bearers; and (c) on other grounds - unemployed persons registered by the Employment Office, users of basic social care rights, war-disabled soldiers, disabled civilians from the war, family members of the insured who serve in the Army of the Republic of Macedonia, persons who are in prison, or are sentenced to correction measures,

persons who have been hired and imprisoned for the ideas for sovereignty of Macedonia and it's independence as a state, Persons in religious communities (monks, nuns) etc. (1,6).

Citizens who are not included in any of the above-mentioned groups, because of various reasons, can voluntary obtain obligatory health insurance, for themselves and for the members of their families, by paying the health insurance contribution in accordance with the Law.

The obligatory health insurance, apart from covering the active insured (bearer of insurance), also covers his/her close family members: spouse and children up to the age of 18, or to the age of 26 if they are students involved in regular education. In addition to the citizens of the Republic of Macedonia, obligatory health insurance is also valid for foreign citizens and individuals without any citizenship, if they are employed on the territory of the Republic of Macedonia, in domestic or foreign firms, in international organizations or diplomatic residencies, or if they are involved in an expert training or education in the Republic of Macedonia. Foreign citizens from countries having international agreements with the Republic of Macedonia for social insurance, use health care rights according to those agreements (1,6,7).

The expenses of the health care services for the citizens of the Republic of Macedonia who do not undergo any form of the obligatory health insurance, i.e., who are not Fund insurees, are covered by the State budget in the following cases: (a) health care of children and adolescents up to the age of 18, and pupils and students up to the age of 26; (b) health care of women related to pregnancy and delivery; and (c) treatment of infectious diseases, mental diseases, rheumatic fever with complications, malignant diseases, diabetes, chronic dialysis, progressive nervous and muscle diseases, cerebral paralysis, multiple sclerosis, cystic fibrosis, hemophilia, thalassemia and similar diseases, epilepsy, alcoholism and drug addiction (1,6).

Rights from the Obligatory Health Insurance

Health Insurance Fund provides the right to health care, as well as the right to a sick-leave and other financial reimbursements to the insured (1,6,7).

The obligatory health insurance, on the principle of solidarity as a key element for providing the health care rights, provides the insured with the following basic health care rights / benefits or „basic package of health care services":

I. Health care rights/benefits at the Primary Health Care (PHC) level: (a) medical examinations and other kinds of medical assistance in order to determine the diagnosis, follow-up, or check the health status; (b) undertaking expert medical measures, other measures and procedures for promoting the health condition, i.e. prevention and early detection of diseases and other health disorders; (c) providing emergency medical assistance; (d) outpatient treatment or home care treatment at the user's home; (e) health protection related to pregnancy and delivery; (f) implementation of preventive, therapeutic and rehabilitation measures; (g) prevention and treatment of oral and dental diseases; (h) providing medicines in accordance to the List of medicines, issued by the HIF and approved by the Minister of Health;

II. Health care rights/benefits at the Specialist-consultative Health Care level: (a) examination of the health status of the insured and establishing diagnosis and giving recommendation for further treatment; (b) performing specialized diagnostic, therapeutic and rehabilitation procedures; (c) prosthetic, orthopedic, and other facilities, supporting and sanitary instruments, and dental technical devices according to the General Act issued by the HIF and approved by the Minister of Health; and

III. Hospital (in-patient short-term and long-term) services: (a) examination of the health status, providing treatment, rehabilitation and care, accommodation (in standard conditions - hospital room with two or more beds) and meals during hospitalization; (b) providing medicines in accordance to the List of medicines, issued by the HIF and approved by the Minister of Health, as well as supporting materials for application of medicines and sanitary materials needed for treatment; (c) accommodation and meals for the accompanying person of the child up to 3 years of age, during hospitalization, if necessary up to 30 days (1,6,7).

The following services are not covered by the obligatory health Insurance and might be a subject to the voluntary health insurance: (a) aesthetic surgery, sanatorium treatment and medical rehabilitation of certain chronic non-communicable diseases (except for children up to 18 years of age); (b) in-patient health services with higher standard or comfort; (c) medicines not included in the List of medicines determined by the HIF and approved by the Minister of Health; (d) orthopedic facilities and instruments not included in the list prepared by the HIF and approved by the Minister of Health, or made of higher standard of materials; (e) accommodation and care in gerontology facility etc. (1,6,7).

In addition to the basic health care rights, the obligatory health

insurance also provides some other rights to the active insured: (a) reimbursement of salary due to illness or injury, medical examination, voluntary donation of blood or biological tissues, during the sickness leave or due to the pregnancy and maternity leave for 9 months, as well as for the care of a sick child up to age of 3 years (no limit) or other family member (up to 30 days); (b) all insured have the right to the reimbursement of the travel expenses for usage of health services, and some other reimbursements (1,6,7).

Realization of the Rights to Health Care

The obligatory health insurance rights are used by the insured and their family members through Health Insurance Fund on the basis of the issued health book, and a confirmation of paid health insurance contributions (blue tickets/marks) (1,6,7,8).

The insured person has a right and obligation to choose a physician (doctor of choice) within the appropriate service at the PHC level (Service of general medicine, Occupational medicine, Service for health care of the children up to 6 years of age or School medicine for school children and adolescents up to 18 years of age, and students au to 26 years of age, Service for health care of the women related to their reproductive functions, for women over 14 years of age, and Dental service for general dental care, for all insured). The doctor of choice is responsible to follow the health status and to provide preventive measures and activities for health promotion and prevention and early detection of diseases, as well as treatment of diseases and injuries, to determine the need for sickness leave and referral of the patient to the higher levels of the health care system, if necessary.

Basic health care rights might be realized on all levels of the health care system as follows: 1) primary health care, including general practice, occupational medicine, pediatrics, school medicine, gynecology, and general dental practice; primary health care also covers emergency medical assistance and home treatment; 2) consultative-specialist health care provided in health centers and medical centers; 3) sub-specialist health care provided at the clinics and institutes of the Medical Faculty in Skopje and some other health institutions at the national level; 4) hospital health care; and 5) medical rehabilitation at outpatient services, medical centers, and hospitals during the hospital treatment, as well as, specialized medical rehabilitation in specific rehabilitation centers as a continuation of the hospital treatment (7).

An insured has a right to the treatment in a foreign medical institution if the disease can not be treated in the Republic of Macedonia and if there is a

possibility for a successful treatment in some foreign country. The conditions and procedure for sending the insured abroad for health care treatment are regulated precisely by the General Act of the HIF approved by the Minister of Health. Physician recommendation and the approval for treatment abroad by the Health Insurance Fund Committee is required before granting the insurance coverage. Coverage for services obtained abroad that are available in Macedonia is not provided, in order to protect against erosion in utilization of Macedonian medical care (1,6,7,9).

Resources for Health Financing

Health care system services and certain broader public health activities are financed by the monthly payroll (profit) contributions of the employed persons in public and private sector and contributions from the general budgetary revenues, external assistance and limited imposition of users fees (1,6,10,11). Most of the revenues (over 90%) are raised from the health insurance contributions in accordance with determined rates. About 57.4% of domestic health sector revenues, in the year 2002, were derived directly or indirectly from payroll contributions to the Health Insurance Fund. Direct contributions from public and private sector wage-earners (all persons engaged in different forms of socially organized or personal labor) were equal to 8.6% up to June 2001 when the contribution rate was formally increased to 9.2% because of the changes in the basis and the way of calculation of the health insurance contributions. In fact, this change was induced by the decrease of the personal income tax (as a part of the gross wages) from 23% to 15%, which means that the real contribution for health insurance by rate of 8.6% and personal income tax of 23% is about equal to the contribution by rate of 9.2% and personal income tax of 15% within the gross earned wages and reimbursements during sickness leave (12). Direct payroll contributions to the Health Insurance Fund were withheld from the source (employer).

Certain percentage of money from payroll contributions to the Pension and Disability Fund and the Employment Fund is transferred to the Health Insurance Fund for health coverage of the retired/pensioners, disabled and eligible unemployed persons. For pension beneficiaries, the contribution rate (14.694%) is applied to the net pension reimbursement, while for the unemployed and for the recipients of social assistance, the contribution rate of 8.6% is applied to 65% of the average net salary in the country to the insured from „social categories" in case they are not employed. These funds are transferred to the Health Insurance Fund by the Pension and Disability Fund, the Employment Fund, and by the Ministry of Labor and Social Policy. About 22%

of domestic health revenues in 2002 were transferred from the Pension and Disability Fund, and about 12.6% from the Employment Fund. Farmers have to contribute 9.2% of the cadastre income. For the citizens with a private enterprise and their employees, the rate is 9.2% of the gross earned wages and reimbursements. Additional contributions for health insurance in case of injury at work and professional disease, for the employees in public and private sector who are exposed to an increased risk for injury at work and professional disease, are determined by rate of 0.5% of the gross earned wages and reimbursements (6,10).

The general budget was also a negligible source of revenue for the health sector until 1992, when financing of the most prevention programs was shifted from Health Insurance Fund to the budgetary financing. The general budget in 2002 accounted 5.9% of domestic health revenues, which is remarkable increase comparing with 1996 when accounted about 3.5% (5,13).

Revenues generated through user fees for health services and applied devices in the public health system amounted 1-2% of domestic health revenues.

User Participation in Health Care Expenses (Co-payment)

The insured and their family members for the health care have to pay from their personal funds a certain percentage of the health services price, but not more than 20% of the total cost of the health service or drug. In 2001 HIF came to a decision about the level of user's participation in the health care expenses, as follows: (a) 10-20% of the price of health services and of medicines at the PHC level; (b) 10-20% of the price of health services for treatment of oral and dental diseases (except prosthetic devices); (c) 10-20% of the costs of services in the specialist-consultative care and hospital treatment, including all costs for services and medicines; (d) 20% of the total expenses for approved treatment abroad; (e) 20-50% of the price of hearing and visual (eye's) facilities; (f) 20% of the costs of dental prosthetic devices; and (g) 20-50% of the price of some other prosthetic devices in accordance with the General Act issued by the HIF and approved by the Minister of Health (6,11,14,15).

Introducing co-payments for health care services and drugs was one of the most controversial questions in Macedonia after gaining the independence in 1991. An attempt of the Ministry of Health, through Health Protection Law in the 1991, to introduce co-payments on all goods and services covered by the health insurance, was struck down by the Constitutional Court as infringing on the fundamental rights to health care. In order to erase financial constraints in

the health sector, Ministry of Health once again, by the 1993 Amendment, proposed co-payments on all insured goods and services (20% for outpatient care, drugs, hearing aids and dental devices; 10% for hospital care; 50% for prosthetic and orthopedic devices). The Amendment was adopted. 2000 Health Insurance Law continued this practice for co-payments by introducing a general principle of adversity of the level of user's charge and the price of a service or drug. It means that the co-payment rate / percentage is higher for the lower price services, but not more than 20% of the service / drug price, and the opposite, lower co-payment rate for the higher price services / drugs (1,5,6,11).

There is no co-payment for health care in the following cases: (a) follow-up of the health status of the insured by the physician of choice, and for emergency medical services on call; (b) users who receive permanent social assistance, persons placed in the institution for social protection or in other family, except for medicines prescribed at the PHC level and for the treatment abroad; (c) psychiatric patients placed in psychiatric hospitals and persons with mental retardation without parent's care; (d) insured who, during the calendar year, have paid user charges for specialist-consultative and hospital treatment (except for medicines prescribed at the PHC level and for treatment abroad) in cumulative amount over 70% of the average income per month in the country in the previous year. Certain age categories of citizens might be excluded of co-payment when they reach reduced level/limit of user charges paid during the year; (e) additional exemptions, in accordance with some special health care programs with social dimensions and related to the entire population, adopted and financed by the Government of the Republic of Macedonia each year, are determined for users of health services in relation to the treatment of certain debilitating, costly, and often life-threatening diseases (rheumatic fever, progressive nervous and muscle diseases, cerebral paralysis, multiple sclerosis, cystic fibrosis, epilepsy, penfigus, lupus erithematodes, infectious diseases - list of about 20 diseases, drug-addiction and alcoholism, up to 30 days, chronic dialysis, conditions after transplantation of the organs, malignant diseases, hemophilia and diabetes, hormones for growing-up the children and compulsory immunization); (f) prosthetic, orthopedic and other devices for children up to the age of 18; (g) women in relation to pregnancy and delivery; (h) infants, up to one year of age; (i) blood donors who voluntary have donated blood more than 10 times; and persons exempted by some special regulations (war disabled persons or family of soldiers who were killed in action), (6,11).

Payment to the Health Care Providers

According to the Law on Health Insurance, health care organizations and the HIF are obliged to plan the necessary funds for providing health care services and realization of the rights to health care to the insured coming from the obligatory health insurance. Each year HIF prepare a plan and program for health services to be financed from the obligatory health insurance, as well as determine criteria, by the General Act approved by the Minister of Health, for contracting with health care organizations and for the ways of payment to the providers of health care services (6,16).

According to the Law in Health Insurance, there are three basic methods of payment to the providers for health services: (a) number of insured persons registered for health care on the list of the physician (doctor of choice) at the PHC level (capitation); (b) determined price for each unit of health service or intervention (fee-for-service); and (c) programs for certain kinds of health services. In addition to that, HIF determine some other criteria for coverage emergency medical services for entire population, home visits by nurse (patronage) to pregnant women and babies regardless to the status of insurance, providing continuous health care during the day and night (24 hours) and during the holidays and weekend days, etc. The Law doesn't make any difference between public and private health care providers, in relation to the possibilities for contracting with the HIF, in order to provide equal financial conditions and incentives for efficient performance in delivering health care, for both types of providers (6,17).

Revenues and Expenditures of the Health Insurance Fund in the Year 2002

The revenues of the HIF are used to fund the programs for which the HIF is responsible and to finance the government's share of the health insurance costs for those enrolled in the program. Direct contributions by employers and workers for health insurance were 57.4% of the total HIF revenues in 2002 (Table 1). In addition, their contributions to pension and unemployment benefits include components that are used for health insurance premiums for persons who are retired, unemployed, disabled veterans, or recipients of social (welfare) benefits. These amounts, which were about 35.1% of the HIF revenues, are paid by the state Funds for Pension, Unemployment, and other social programs. HIF revenue from the general budget in 2002 accounted 5.9%.

Table 1. Revenues of the Health Insurance Fund of the R. Macedonia 2002 (In 1000 denars) (18,19).

SOURCES OF REVENUE	BUDGET PLAN	ACTUAL	PERCENT VARIANCE	STRUCTURE (%)
1. Employee's gross salaries	6,498,120	6,755,479	104.0%	48.4%
2. Self employed	268,856	225,640	83.9%	1.6%
3. Farmers	60,258	60,369	100.2%	0.4%
4. Additional contributions (workers at risk)	372,228	432,890	116.3%	3.1%
5. Other insured	101,112	101,335	100.2%	0.7%
6. Contributions from previous years	450,275	435,957	96.8%	3.1%
Total employment revenue	**7,750,849**	**8,011,670**	**103.4%**	**57.4%**
7. Pension fund	2,945,560	3,074,632	104.4%	22.0%
8. Unemployment fund	1,759,523	1,763,354	100.2%	12.6%
9. Social, veterans, disabled funds	52,000	53,582	103.0%	0.4%
10. Budget	489,769	821,259	167.7%	5.9%
Total transfers	**5,246,852**	**5,712,827**	**108.9%**	**41.0%**
11. Other revenue	232,776	241,496	103.7%	1.7%
12. Transfer from previous year	95,886	95,886	100%	—
TOTAL REVENUE	**13,326,363**	**14,061,878**	**105.5%**	**100%**

Health care expenditures of the HIF in 2002 are about 83.2% of total expenditures. Salary reimbursements accounted another 6.5%, and the capital investments 6.3% of the total HIF expenditures (Table 2). The structure of the health care services expenditures of the HIF in 2002 is presented on the Table 3. Outpatient services at the PHC level accounted for about 18.2% in comparison with higher outpatient specialist-consultative health care services 23.6% and hospital care / services with 42.6%. Prescription drugs were 9.9% and dental care expenditures 4.3%.

Table 2. Expenditures of the Health Insurance Fund of the R Macedonia, 2002 (1000 denars), (18,19)

EXPENDITURES	BUDGET PLAN	ACTUAL	PERCENT VARIANCE	STRUCTURE (%)
Health Care Expenditures	11,353,834	11,629,454	102.4%	83.2%
Salary Reimbursements	876,661	908,648	103.6%	6.5%
Orthopedic devices	135,000	112,813	83.6%	0.8%
HIF Operating Expenses	426,189	331,648	77.8%	2.4%
Capital Investments	441,679	875,070	198.1%	6.3%
Capital Transfers	33,000	25,482	77.2%	0.2%
Past-Year Obligations	60,000	88,004	146.7%	0.6%
Total Expenditures	**13,326,363**	**13,971,119**	**105.0%**	**100%**

Table 3. Structure of the Health Care Services Expenditures of the Health Insurance Fund of the Republic of Macedonia, 2002 (1000 denars), (18,19)

EXPENDITURES	BUDGET PLAN	ACTUAL	PERCENT VARIANCE	STRUCTURE (%)
Outpatient services (PHC)	2,487,332	2,113,607	85.0%	18.2%
Specialist-consultative health care services	2,310,770	2,750,143	119.0%	23.6%
Dental care	530,730	499,856	94.2%	4.3%
Hospital care/ services	4,449,330	4,953,327	111.0%	42.6%
Other health care services	21,000	19,597	93.3%	0.2%
Prescription drugs	1,250,437	1,149,804	92.0%	9.9%
Treatment abroad	130,000	143,120	110.1%	1.2%
Program related expenditures	174,235	–	–	–
TOTAL	11,353,834	11,629,454	102.4%	100%

Health Insurance System in the Health Care Reform in Macedonia

After its newly gained independence in 1991, the Republic of Macedonia inheritance from the social system of the former Yugoslavia was a social model of obligatory health insurance and highly decentralized and locally funded public health care system. The main weak points of the system were tendency toward further fragmentation and duplication of unsustainable services, excessive staffing that exacerbated the duplication of care, interregional differences and inequities in the amount and quality of care. That system became unsustainable, particularly in actual economic circumstances and economic transition. Up to 1991, there were 35 independent Self-management communities of interest for health care on the municipal level and one on national level. All of them were replaced by a single centralized Health Insurance Fund within the newly created Ministry of Health, with branch-offices of the Health Insurance Fund on the local level. Centralization was an attempt aimed, first of all, for stronger control of resource utilization and more equitable distribution during the transition period and economic crisis.

In the period after 1991, both the health insurance system and health care system, were faced with numerous problems, as a result of: (a) the war conditions in former Yugoslavia, (b) the economic and transportation blockades; (c) drained inflow of funds from health services given to patients coming from other places out of Macedonia; (d) the decreased funds from the insurance for more than 40% in real terms, due to the great number of unemployed persons, breakdown of socially-owned enterprises, and reduction of employee income; and (e) different types of tax evasions and other manipulations with obligatory health care payments (5).

Total national health expenditure, expressed as a percentage of GDP, decreased from 6.2 in 1990 to 4.8 in 1992, compared with 7.6% of GDP in 1998 and 4.7% in 2002. Per capita health spending decreased from US $66.8 in 1990 to 39.2 in 1992, compared with US $97 in 1998 and US $93,3 in 2002 (5,13). Salaries were a fixed expense and this caused a serious shortage of supplies and equipment for primary health care.

Thus, at the very beginning of the independence, there emerged an inevitable necessity to undertake urgent measures to prevent further erosion of the health system, provide sustainable volume and quality of the health services, and introduce urgent long-term reforms of the health care system and health insurance system. The Health Protection Law, adopted in 1991, also authorized private health services and pharmacies but did little to streamline the public health system, create incentives for increasing efficiency, or define

legal and regulatory environment for the private providers. Shortages of medications were mitigated only modestly by humanitarian assistance, which covered the essential needs for medicines and medical materials. Negotiations with the World Health Organization and the World Bank were also initiated to acquire loans and technical support for the implementation of the health sector reforms. In 1993, Ministry of Health undertook activities for a reform process aimed mainly at: (a) allocating the resources on areas with an immediate impact on the health status of the population and maintaining the basic health services operational through provision of adequate drugs and other consumables; (b) undertaking structural reform and reorganizing of the health care system; and (c) facilitating privatization and development of private health services in order to stimulate competition and improve quality of care and health services (4,5).

Ministry of Health asked the World Bank for assistance for further implementation of the reform, and Macedonia became a member of the World Bank in December 1993. The Health Sector Transition Project was the first funded project of the International Development Association of The World Bank in the social sector in the Republic of Macedonia, and the first donor intervention for reform and restructuring of the health sector.

One of the components of the health care reform strategy was financing. It included defining the reforms in pricing policy, benefit packages, and reimbursement mechanisms for ambulatory and hospital services. The objective was to develop new policies and mechanisms which would: (a) maintain broad access to care; (b) create financial incentives for efficiency and cost containment; and (c) remunerate public and private providers equally on the basis of the performed services. Co-payments for health care services were introduced in 1993 as an alternative option for supplementary funds, as well as to prevent excess utilization of services, but because of the wide range of exemptions (determined by age, sex and disease) the financial effects were very poor (only about 4-5% of the revenues of the health institutions). The long list of exemptions proved that users fees were not only unlikely to be an affective policy mechanism to collect revenues but, more importantly, they encouraged greater use of health care services for exempted groups, with associated higher costs for the Health Insurance Fund, especially in cases certain health conditions involving extensive and costly care. Those provisions had substantially weakened the initiated impact of the participation policy (5).

During 1991-1995, the revenues collected from contributions decreased by approximately 40% in real terms as a result of lower salaries,

bankruptcy of socially-owned enterprises, and evasion of payments by many enterprises, and, of course, increased unemployment. Consequently, the revenues of the Health Insurance Fund significantly decreased, resulting in decreased funding of the health care institutions. Regardless of all the efforts, the expected results did not come and, in the end of 1994 and the beginning of 1995, Health Insurance Fund entered a very difficult phase, with obvious symptoms of breaking down the health system, which was built over for a very long period of time. In early 1995, with the assistance of local and foreign experts and in cooperation with the World Bank, an urgent analysis of the conditions in the health system was made, and a strategy for undertaking sanitation measures was established, simultaneously determining the short-term measures and activities for long-term reform of the health sector. The health care system was analyzed in three segments: (a) financing and management; (b) primary health care and health promotion; and (c) supply of drugs and medical materials. The primary objective was to find the most appropriate solutions for redesigning the health care network and functions of the system in order to meet the demands of the citizens for high quality health services (5,20).

An extreme rationing of medication and medical necessities and other material expenses of all health organizations was undertaken by organizing tenders and bidding for central purchase of drugs, sanitary materials and equipment, which resulted in price reduction. In order to achieve equal distribution a central pharmacy store was formed, which, according to the Health insurance financial reports for 1995 and 1996, saved millions of dollars, or about 20% of the funds spent on the same materials during the period up to 1994. The competition principle and competitive conveniences for more efficient and rational provision of health services were introduced. This was made possible by the newly imposed legal opportunity to sign an agreement with private organizations and with health professionals for providing health services by personal labor at the account of Health Insurance Fund and in accordance with the norms and standards. This created possibilities for more economic performance of health services. Many other organizational measures were also undertaken, which started to improve the global financial situation of Health Insurance Fund (21,22).

The main principle of the reallocation mechanism of the funds from Health Insurance Fund to health institutions was financing on a contractual basis and invoicing of services according to the official price list. This principle was implemented only for financing the private health sector. The public health institutions expenditures were covered by the Health Insurance Fund in

order to cover the wage costs, material costs and maintenance, even without signing any contract for the scope and quality of the services. Because of this, measures to restructure organization and management in the public health sector were delayed, and the quality of health services and motivation of the health workers decreased, resulting in an inefficient use of the resources.

The previous system of referral practice, i.e. in a necessity of a written referral to the specialist from primary health care physician, was abandoned soon after Macedonia gained independence, as part of the changes in the socio-economic and political context and general movement to increase personal freedom and freedom of choice. This aggravates the budget problems to the Health Insurance Fund because of the increase in specialist costs and hospitalizations. By 1995, amendments to the Health protection law re-established the referral practice by providing direct specialist-consultative and hospital health care only in emergency cases. The same revision of the Law requires that each insured person selects a primary physician from the same municipal area, who will be responsible for the follow-up of the health status of the insured, provision of medical assistance, prescription of medicines, issuing the certificate for sick leave and referral to higher level services. The physician has been chosen from one of the following fields/ disciplines: general medicine, occupational medicine, pediatrics, school-age children medicine or gynecology. However, a widespread opinion is that many primary physicians are still more „traffic policemen", directing patients toward specialists, than „gate keepers", motivated and empowered to treat and cure broader scope of illnesses and conditions. According to the results of a survey done by the Doctors' Chamber of Macedonia in 1998, low payments and bad working conditions caused frustration and low self-esteem of the physicians, as well as low motivation and satisfaction with their work (the average salary of the general practitioners in 1998 was about US $200) (5).

In 1996, comprehensive health care reform was undertaken when the World Bank awarded the Ministry of Health of the Republic of Macedonia a loan of US $19,4 million. The basic goals of the reform were to achieve universal access to high quality primary health care and establish cost effective finance and delivery systems. The initial reform efforts were supported by a grant from the World Bank. Technical assistance was provided by the RAND Corporation from the USA. They joined a team with policy-makers of the Ministry of Health, Health Insurance Fund and other health professionals in the Republic of Macedonia in order to initiate reform analysis and create new strategies. The proposed new health care policies were directed to

the following specific objectives: (a) identification of the health care priorities in the Republic of Macedonia through assessing the burden of diseases and effectiveness of available treatment; (b) reduction of the overall health expenditures and put them in balance with revenues; (c) shifting health care utilization patterns away from expensive forms of care; (d) producing a benefit package that is more cost-effective and co-payment structure that improves sectoral efficiency in order to reduce the existing gap between financial resources and given health benefits to the citizens; (e) developing a capitation plan for primary health care providers and concept of family medicine in primary health care, or reorganize the concept of general practitioner's; (f) establishing an integrated and automated health information system as a support for better management in health care system; and (g) proposing an advocacy information strategies that facilitates the reform process.

In the last five years, activities have been taken for implementation of the principle of capitation within the primary health care level, for strengthening the citizen's right for choosing the doctor and creating a basic package of health care services, as well as fee for service payment on the secondary and tertiary level according to the official price list. To support these activities, adjustment of the health information system and management of the health institutions through training of the managers and other employees was introduced.

However, the activities for acquiring humanitarian aid and other kinds of support did not stop. Macedonia also entered several programs of the European Union (PHARE) for solving few substantial problems through non-refundable financing. It must be emphasized that all undertaken measures and activities resulted in partial and temporary alleviation of the problems during the painful transition period in the Republic of Macedonia.

The most recent activities within the reform of the health insurance system were directed to the preparing of a new Law on Health Insurance, which has been adopted by the Parliament of the Republic of Macedonia on March 30 and enforced on April 7, 2000. The Health Insurance Fund was established as an independent institution outside of the Ministry of Health. The Executive Board of the Health Insurance Fund already adopted many general acts, approved also by the Minister of Health, which approach in more details the most important issues for efficient implementation of the Law in practice, i.e. strengthening the mechanisms for collecting of regular revenue for the Health Insurance Fund, introducing methodology for calculating the new methods of user participation in health care expenses (co-payments), as well as

more precise regulation of the relationships within the health insurance related to the obligatory and voluntary insurance, the categories of the insured persons and their rights and obligations, and the scope of activities and responsibilities of the Health Insurance Fund.

EXERCISE: Specificities of the Current Health Insurance System in the Republic of Macedonia

Task 1: Comparing health expenditures between countries

Students should collect data about Health Care Expenditures from their respective countries. In addition to that, they have to be compared with Macedonian expenditures. An analytical approach about the percentages of the funds spent on Primary Health Care, Hospital Care, Medicines, Treatment abroad etc. will be considered through group discussion.

Time proposed is 60 minutes.

Task 2: Health Insurance System

Students are asked to collect some specific indicators (HFA Database and other sources) and readings about Health Insurance System in their respective countries in order to prepare a seminar paper as practical work.

This task will be done individually, as homework.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Case Study: SWOT Analysis of the Serbian Health Insurance System**
Module: 2.7	**ECTS (suggested): 0.25**
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Keywords	Health insurance, management, SWOT analysis, change
Learning objectives	At the end of this module, students should be able to analyze present status of health insurance management by using SWOT analysis and to propose possible changes and improvements.
Abstract	The reform of health system must inevitably reconsider the management of all institutions, such as health insurance institutions. The first step in this process is to analyze the present status. One of the tools used for this assessment is SWOT analysis.
Teaching methods	After reading the case study, students will work in small groups and produce written recommendations.
Specific recommendations for teachers	It is recommended that this module is organized within 0.25 ECTS credit. The work under supervision is consisting from case study, small group discussions, while individual work is related to review electronic and printed literature in the field.
Assessment of students	Written report produced by each group.

CASE STUDY: SWOT ANALYSIS OF THE SERBIAN HEALTH INSURANCE SYSTEM

*„When a manager leads from one crisis to another, it is time for the next manager"**

Vesna Bjegović, Adriana Galan

Current trends in health care system reforms

At present, almost all the countries, including the developed ones, are facing the problem of health care system reforming. The reform of health sector is a multidimensional process. As noticed in the reform strategies in other countries, „one part of the scale involves administrative and managerial pressure for cost-containment, and the individual citizen wanting the best possible care at the moment of utilization. At first sight, there seems to be an insoluble dilemma between the two respective opposites" (1). However, one of the WHO experts for health system reforms vividly observed, „since citizens are the final payers of any health care service - public or private - it is in their interest to spend a dollar, mark or ruble for health in the most efficient and effective manner, and for real priorities" (1). This is actually one of the basic management principles, which has been neglected in health care for a long time. Consequently, the reform of health system must inevitably reconsider the financial component, regardless of the model applied, in order to ensure maximal benefits with minimal investments (2,3).

A theoretical approach for the management of health insurance is neither unique for all countries, nor is in place an optimal management structure that is reproducible, since it is dependent on a number of factors like (4):

- the level of political independence of health insurance funds,
- possibility of choice for potential insured persons, between one or several health insurance funds,
- organization of health care services (whether health care providers are employed by health insurance companies or are under contracts for providing health services with insurance),

* Wahba AW. „Appropriate Technology". The Road to Happiness.2nd Edition. Copenhagen 1985: p. 43-9.

- historical factors (existing administrative structure of the Ministry of Health) and country's political system (federal state, centralized state, level of political responsibility etc.),
- economic and social situation of the country,
- health policy objectives that need to be achieved by health insurance.

The basic trends in the reforms of health care financing in the European Community countries, both developed and developing, have been determined by factors related to a decreasing role of the state and introduction of a controlled market, reorganization of the whole health care system in terms of decentralization, re-centralization and privatization, civil rights, individual's choice and participation, as well as enhancing the role of public health (5).

Historical background of the Health Insurance System development in the Republic of Serbia

The Health Insurance Law in Serbia passed the Parliament in 1992. According to this Law, the Health Insurance System was established, with mandatory health insurance for the whole Serbian population. The Republic Health Insurance Fund was then created, having a „declarative" independent statute. This national company has 30 subordinated branch offices located in each district of Serbia.

According to the above-mentioned Law, the managerial board of the Republic Health Insurance Fund consists of the following structures: the Insured Representatives Body, the Managerial Board, the Director and the Supervising Board (6). The Insured Representatives Body consisted mainly of insured persons' representatives.

In 1998 the Law from 1992 was modified and amended. This amended Law dissolved the Insured Representatives Body, and a formally representative body of the insured population replaced it. By these amendments, the shift towards a complete centralization of the health insurance management, only perceptible in the Health Insurance Law from 1992 or various Governmental Acts has gained finally a complete legal support. The present managerial structure of the health insurance institution in Serbia, being completely dependent of The Government of the Republic of Serbia, consists of: The Managerial Board, The Supervising Board and the Director. This structure is presented in Figure 1.

The Director and Vice-Director are directly appointed or set free by the Serbian Government, while the Managerial Board and the Supervising

Board are elected on the basis of proposals made by the insured' representatives: The Serbian Trade Unions, The Association of Pensioners, the Cooperative Association of Serbia, The Serbian Chamber of Commerce and the Director of the Republic Health Insurance Fund. The Managerial Board consists of 21 members, out of whom 14 are the insured representatives (from the employees category), 2 insured pensioner representatives, 2 insured farmer representatives, 2 insured independent activity representatives and one company employee representative, respectively.

This case study is based on SWOT analysis in order to depict the Strengths, Weaknesses, Opportunities and Threats in the Serbian Health Insurance System Management.

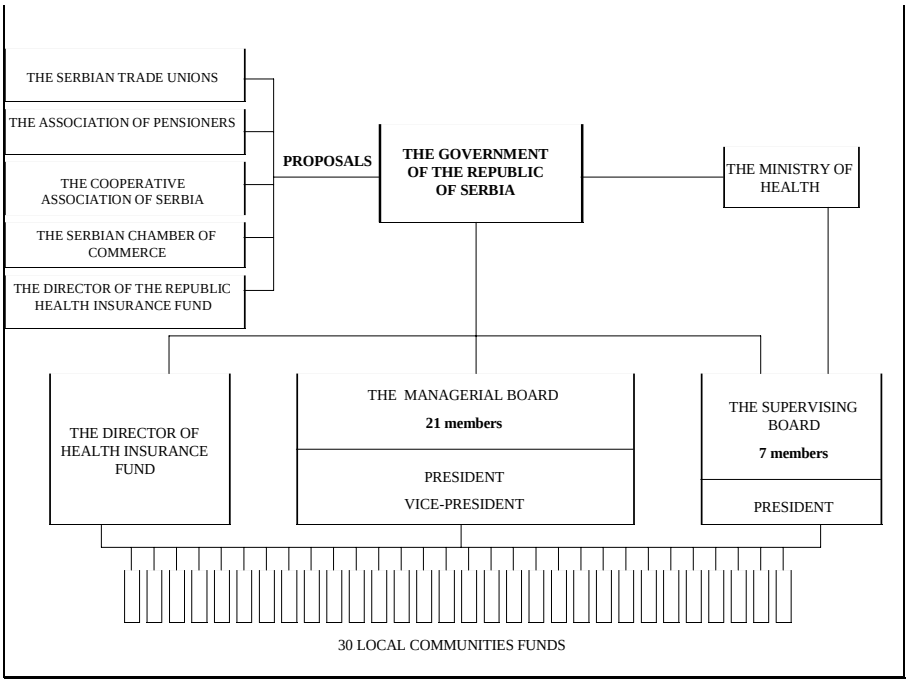

Figure 1. Organizational structure of health insurance system in the Republic of Serbia

Strengths

All former Republics of Yugoslavia were much earlier than other SEE countries experiencing some kind of health insurance system. Serbia started to change the old type of insurance system „based on Self-management Community of Interest" in 1989, and afterwards in 1992 when the Health Insurance Law passed the Parliament. It was a radical change in the financing of Health Care System.

The existence of such kind of health care financing is one of the basic strengths because the physical infrastructure for the present 30 local branches was already in place. In this way, no additional funds were necessary to create this infrastructure.

At least, at a declarative level, the insured persons are well represented in the Managerial Board of the Republic Health Insurance Fund according to the Health Insurance Law from 1992.

Another positive aspect of the present managerial structure is that the administrative body is relatively small, since the total number of employees in the Republic Health Insurance Fund, including all branch offices, is 1921 (7). Although the number of employees may appear to be high, it is in fact far smaller than in other systems having a longer tradition of health insurance, with less number of insured. For example, according to the data available from 1998, there were 2621 registered insured persons per an employee in the Republic Health Insurance Fund. This is low compared to Germany for instance, where commonly the number of registered insured persons per an employee in health insurance ranges from 220 to 690 (4). Although there were no studies to evidence the motivation of the employees, or the level of their skills for specific jobs, qualitative methods (e.g. financial policy analysis) have revealed that the number of employees is yet insufficient for achieving effective and good quality results.

Weaknesses

Since the beginning, the health insurance system in Serbia was characterized by a marked centralization and a strong dependence in the process of decision-making on other governmental authorities (even outside of the health care system). Such „quasi-autonomy" of the health insurance and its strong political dependence prevent any initiative or enterprising, and the management effectiveness has been additionally decreased by strict and often out of date legal regulations.

From organizational point of view, it can be noticed that the branch offices of the Republic Health Insurance Fund have actually no responsibility of managerial decision-making. They don't have even a uniform organizational structure.

The representative body of the insured within the Health Insurance Fund Board has an inadequate structure according to the existing consumer categories. It is unbalanced in terms of the number of the insured (one mana-

gerial body per around 7.5 million of potential consumers) and local consumer representatives (from 30 local communities) are not allowed to participate in the decision-making process for adequate allocation of the financial resources collected in their own territory. In this way, the stipulations of the supreme legislative Act at the Republic level - The Constitution of the Republic of Serbia from 1990 - have not been achieved (Articles 40 and 68) which guarantee the participation of each citizen in the decision-making process related to mandatory social insurance (8).

The mechanisms of delegating the Managerial and Supervising Board representatives are not democratic and furthermore, they are not based on the real structure and number of the insured paying the contribution for health insurance. For example, 14 insured representatives within the employee category are proposed by the Serbian Trade Union. Even if this is the biggest trade union, it is not the solely one representing the interests of all insured employees. A big number of employees belong to other Unions like the Trade Branch Unions „Independence", the Association of Independent and Autonomous Unions of Serbia, the Independent Unions of Serbia and many others. It can be also mentioned that, unlike other European countries (4), the Managerial Board in Serbia do not comprise health worker representatives.

Management of the present health insurance has not been supported by an adequate information system, although several years ago the Bull HN BG Company designed a major project for its implementation. This was the proposal for the „National Project and Implementation Project for Management and Decision-making Support" within the development of information system of the Republic Health Insurance Fund in 1994, but never implemented in total as it has been planned. According to some estimation, to complete the performance control only in the area of contribution payment, with the existing personnel and without information system, there are needed 20 to 25 years (9). The lack of information system facilitates non-allocated use of the Republic Health Insurance Fund resources, ineffective use of the working hours, and so on. With such rationales, upon a minor revision of the major project, in 1997, there started its practical use - introduction of the health insurance information system, which, unfortunately, failed and ended up with one of the major financial scandals. Nevertheless, local brunch offices succeeded to develop some kind of information systems.

The lack of an information system reduce also the effectiveness of other management functions in health insurance, such as planning, accounting, financial management, external and internal audit. Thus a special problem, recently emphasized, was the lack of relevant, reliable and timely information

for effective management, and monitoring of health insurance functioning at the central level. Such state of affairs enables numerous speculations and is conflicting to the good recommended practices, the health insurance management not being at all transparent for the general public.

Health Insurance staff are very low motivated, neither for quality of work, not for career improvement because of low level of salaries and lack of other incentives.

Opportunities

Due to the scarcity of financial resources available for health care system, it would be necessary to put into practice marketing techniques for the extension of these resources, attracting other funds or obtaining donors aid.

Also, some management techniques in health insurance would be necessary for motivating health care providers to work in a more efficient manner and with acceptance of financial responsibility. Opportunities exist because of positive changes in the postgraduate education for health professionals (continuing education in health management, initiatives to establish a School of Public Health). Additionally, these techniques can also help in better control regular payments of established contributions of insured (particularly employers).

Another opportunity for improving the management of health insurance system can be the adoption of GTZ (Gesellschaft für Technische Zusammenarbeit) methodology, aiming to examine and promote access of all population groups (especially the vulnerable ones) to health insurance system. The German Company GTZ, together with the Institute for Tropical Medicine in Belgium, have developed InfoSure, a standardized evaluation methodology (Health Insurance Evaluation Methodology and Information System). The evaluation is focusing on the following issues: the ways in which health insurance is organized in developing countries; practical experience with the set-up of insurance schemes; sustainability; administrative concepts; experience with certain target groups and special problems. InfoSure consists of a questionnaire and a corresponding software product. The questionnaire consists of three parts: a qualitative one, a multiple choice one and a statistical one for quantitative values. The outcome of the evaluation is a case study. Further, the case studies are processed in an information system, which can be accessed, via the Internet. This methodology permits a comprehensive analysis of a health insurance scheme in order to identify the factors contributing to the success or failure of an insurance scheme (10).

Due to the fact that the political environment became more favorable, the existing Law can be again amended in order to secure an adequate degree of autonomy to the Health Insurance Fund. In this way, there will exist an open door for enterprising, initiative and putting into practice marketing mechanisms for effective achievement of the objectives of health insurance. On the other hand, Law can also regulate decentralization process. This means delegating the management empowerment and responsibility to branch offices at lower organizational level, their legal status being thus regulated by Law. Consequently, transparency can be secured for the consumers, as well as more effective control of quality and costs of health care services provided.

In addition, different international technical assistance (e.g. World Bank, European Agency for Reconstruction, etc.) are in place, aiming to support further changes in improving the management of health insurance.

Threats

Serbia, like other surrounding countries, is marked by a deep economic crisis, inherited on one hand from the past communist regime and extended by the world economic crisis. The poor performance of economy has a deep negative impact on the social sectors, including health and education. Unlike other countries, Serbia has also to face the devastating consequences of the war during the 1990s, which have further deepened the scarcity of resources available for the social sector. It is not foreseen an immediate growth of economic level, therefore the health care system performance has little chances to improve in a short period of time. This is also true for the Health Insurance System. The real income of a large number of households has dramatically decreased, affecting directly the health insurance fund.

Political involvement at almost all administrative levels has also affected in a negative way the proper management of the Health Insurance System. Also the political instability has often induced changes in human resources structure (especially top managers) affecting in this way the continuity of strategic thinking at Republic Health Insurance Fund level.

Potential consumers have still no alternatives to choose among insurance funds, since private insurance appear very slowly in Serbia. There exists only one mandatory health insurance fund, those created in 1992.

Educational system is not yet prepared to properly train future managers of the health insurance system. The future managers working in health insurance system must achieve specific skills, like: knowledge of effective

collection of contributions, how to identify health care rights, how to ensure available services for all insured and how to monitor the quality of care (4).

EXERCISE: How can the Health Insurance Management be restructured?

Task 1: After reading this case study under the supervision of lecturer, students are asked to split and work in small groups (4-6 students) in order to discuss and decide possible recommendations they would make for the improvement of health insurance management in Serbia (2 hours for reading the case study, 1,5 hour for group discussion and 1 hour to produce written recommendations to be presented to the whole group).

Task 2: In the case of a SEE workshop on „Health Care Management and Financing", students are asked to split in country based groups and draft similar SWOT analysis for their own countries, further discuss the similarities and differences and finally make recommendations (3 hours).

References and Recommended Readings

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Economic Appraisal as a Basis for Decision Making in Health Systems**
Module: 2.8	**ECTS (suggested): 0.75**
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Keywords	Health economics, efficiency, economic appraisal, cost-benefit analysis, quality assurance
Learning objectives	After completing this module, students and public health professionals should have an increased understanding of: • health economics as a scientific discipline and the relationship between evaluation and economic theory; • the options to manage scarcity in health care systems; • the key evaluation methods in health economics; • setting up an evaluation; and • how to judge the quality of published economic evaluations.
Abstract	This module gives a short overview on the basics of health economics. Economic appraisal is an instrument for Health Care decision-making, which is influenced by many characters. There are three types of costs: direct, indirect and intangible. Costs and benefits can be calculated in a cost-benefit (CBA), cost-effectiveness (CEA), cost-utility analysis (CUA) etc., depending on society, patient, payer or provider' point of view. When comparing two alternatives, it is important to understand the additional costs and effects. Marginal analysis looks at the extra cost of extra effects in the same programme; incremental analysis looks at the differences between programmes. Alternative projects costs and benefits may occur at different points in time. In order to compare them in a money term, discounting is needed. A discount rate is a number relating the value of one year to the value in the next or previous year. Having unbiased economic evaluation is very important for quality of study. This led to the development of guidelines which regulated many things, but aside of that every reader or decision-maker can make his quality, checking Drummond's „ten commandments" of good appraisal practice.
Teaching methods	After introductory lecture, students will work in small groups, in order to discuss efficiency as a prerequisite for an appropriate health care system. Basic skills like discounting and choosing a decision have to be trained. To do so, financial and mathematical exercises have to be solved (calculated). Students will be learned how to judge the quality of health economics publications that are delivered by teachers.

Specific recommendations for teacher	This module to be organized within 0.75 ECTS credit, out of which one third will be under the teacher supervision. It is recommended that mathematical calculations are prepared. Pocket calculators are obligatory. A selection of publications with different quality levels should be available to the students.
Assessment of students	Multiple choice questionnaire and written design proposal.

ECONOMIC APPRAISAL AS A BASIS FOR DECISION MAKING IN HEALTH SYSTEMS

Helmut Wenzel, Bajram Hysa

The aim of the module is to give a short overview on the basics of health economics and to provide more in depth information on economic evaluation tools (economic appraisal). Current problems of many health care systems as well as approaches to solve those problems are described. Thereafter a short overview on the basics of health economics is given and in depth information on economic evaluation tools (economic appraisal) and their application is provided.

It would be wrong to suggest that health economics is identical with economic evaluation tools like cost-benefit analysis. These techniques are undoubtedly the most relevant and mostly known tools from health economics. This obviously leads to the misunderstanding on the true nature of health economics, then. Today, many health care professionals seem to be familiar with those tools. Nevertheless, it still remains the case that the underlying economic principles and theories are unknown to many. Therefore the paper puts some stress on the economic background of economic evaluation.

Health Care and limited resources

All over the world health policy is faced with an increasing demand and declining financing power at the same time.

Particularly decentralised health care systems are unable to describe the relationship between resources used and outcomes achieved, due to the fact that the amount of money spent is known but the „health production" processes is unknown. As a consequence the efficiency[1] of the health care delivery process cannot be controlled or influenced. Thus, this leads to rationing of services rather than to increasing productivity.

As a first step politicians tend to cut down expenditures by different administrative means. This is followed by reducing the number of covered

[1] In economics, the term 'efficiency' is used when resources (e.g. medical services, drugs, and diagnostics) are used in such a way that nothing is wasted. This means that, in an efficient situation, without adding any more resources, further products can only be produced by sacrificing a quantity of another product.

services (exclusion from reimbursement scheme etc.), and different approaches to lower prices of products.

Health authorities right now are targeting more and more the productivity and the quality of the process of care (or production of health) by promoting *evidence based medicine* - and as an evaluation tool - *outcomes research*.

„*Evidence based medicine* is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (1).

Outcomes research is defined as „assessment of the effect of a given product, procedure, or medical technology on health and/or cost outcomes" (2).

Disease Management (DM) can be described best as „a comprehensive, integrated approach to care and reimbursement based on the natural course of a disease, with treatment designed to address an illness with maximum effectiveness and efficiency (2). If DM concepts are implemented in a proper way, one can assume a less costly but even more effective health care system.

Allocation of limited resources

Are there alternatives to efficient health care systems? If there are more needs and wants than resources available, alternatively two administrative measures could be applied: **Rationing** and **Allocation of resources due to defined priorities**.

In modern democratic societies some questions arise, then:

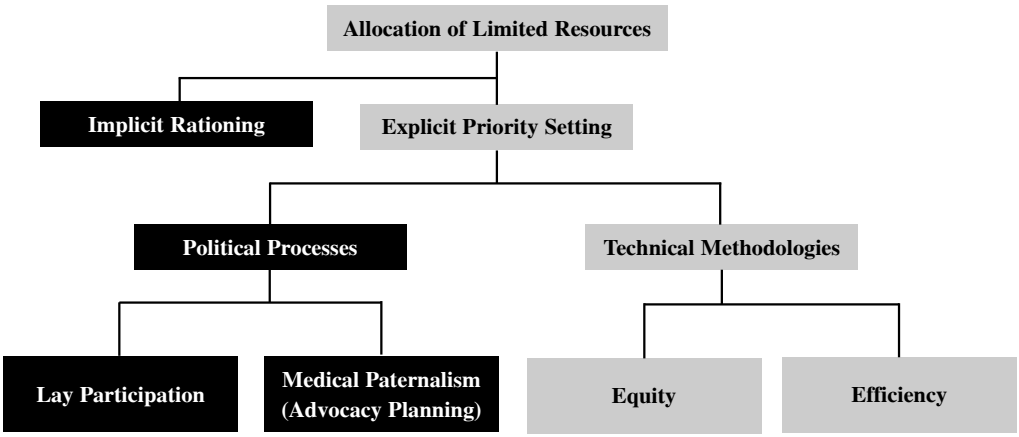
- Who will have the right to define the criteria for rationing or for any priority setting?
- What is the final ethical basis for those decision processes?
- Whose values are the final yardstick for setting up priorities?
- Isn't it even unethical to make those kinds of decisions?

First of all, it is unethical to spend money (resources) in such a way that we do not produce the best outcome in terms of care or - finally health. Overspending in one area (selected diseases, specific patient groups, provision of care like prevention vs. cure) very often goes along with under-spending in other areas. So, it is an ethical must to deal with that problem.

Rationing is an ethical issue as well and ought to be based on the principal agreement of a population. In an *implicit* rationing procedure the decisions and the preferences are not revealed. From the viewpoint of modern societies this is not acceptable. *Explicit* rationing is an outcome of political processes where the consent of society could be received by either lay participation in the decision processes or by the anticipation of the citizen needs by experts. In the late sixties this kind of integrating as many citizen and their needs in any planning process was called advocacy planning. The basic idea was that experts (and politicians) should be able to anticipate the problems of those people that have not the ability to take part in political processes in an adequate way. This approach was not very successful.

For reaching the humanitarian goal of equity, and also more objective ways of comparing the alternative use of modest resources, technical solutions and evaluation tools are inevitable. This is how health economics is coming in. Alternative ways of allocating limited resources are presented in Figure 1.

Figure 1. Alternative ways of allocating limited resources (3)



Source: Coast J. et al., in: Priority Setting: The Health Care Debate, Wiley, 1996

Main Features of Health Economics

Economics is a discipline, a recognized body of thought and not just a set of tools. Consequently, health economics is the discipline of economics applied to the topic of health care, and deals with the factors that determine the individual's demand for health services. Health economics research tries to answer the question what kind of goods and services have to be offered in a health care system, what quality and quantity would be appropriate, and to

what extent services and goods should be produced by public funds (see public goods, Welfare Theory). Moreover, health economics deals with the different ways of financing the health care system, and the system's interdependence with and interconnection to the other sectors of the National Economy. Research tools are coming from different disciplines like: Epidemiology, Statistics, Medicine, Economy (OR, decision analysis, scenario techniques, Game Theory), and modelling.

Economic appraisal techniques (like cost-benefit analyses) are important instruments of this discipline. Those evaluation techniques are going through considerable methodological development, since efficiency gaps in the production of health services still exist. Know-how that comes from other scientific disciplines has been incorporated.

Looking at the very nature of health economics our starting point is simple - *scarcity of resources*, and *the issue of choice*.

Taking a choice means that a decision has to be made not only about what to do, but also what to leave undone. The concept of cost in health economics is different to the concept of cost in accounting, which relates to cash outlays. Therefore, when economists argue that attention should be paid to efficiency in health care, they are implying that health care programmes, treatments and procedures should be compared not only in terms of their relative benefits, but also in terms of their relative costs (i.e. benefits forgone).

Economic Appraisal as an Instrument for supporting Decision Making

As mentioned above, the core of health economics is **choice** and **decision making.** To prepare decision making, information is needed on the desirability of the choice, and the possible outcome in the future. The desirability (or anticipated satisfaction) of a good is described by its **value.** These values have to be put into an evaluation framework that - based on decision rules - recommends what should be done in order to improve the situation in a rational way.

Before explaining the different methods of economic evaluation, a short brush-up is given to introduce the economic concept of value, the theoretical background of deriving and describing value, and the concept of efficiency. These are underlying principles.

The Concept of Value and Efficiency

The *value* of an object reflects its importance with respect to the potential to satisfy the individual needs. This potential is called benefit, or sometimes utility. Economic theory believes in the rational nature of men (paradigm of homo economics). This further leads to the assumption that each individual wants to maximize its degree of satisfaction, which is measured in terms of benefits. In order to maximize the benefits the individual will make sure that the last unit of money spent will create the same amount of benefit.

There are different ways to define and to measure those benefits. Some of those methods are based on the principles of welfare-theory, some are based only on the assumption that men are deciding in a rational way. Other methods incorporate the preferences of patients into the desirability of outcomes.

Generally, efficiency is measured by the relationship between the level of accomplishment of these goals (consequences) and the resources used or expenditures.

There are two simplified viewpoints of efficiency:

- **Cost-efficiency:** product applications or intervention strategies which achieve a given health outcome at the lowest level of resource utilization are called efficient or economical.
- **Output-efficiency:** product applications or intervention strategies which generate the best possible outcome or goal achievement for a given resource input are called efficient or most productive.

Both perspectives of efficiency evaluation include an assessment of both resource input or costs and outcomes. Claiming that a medical intervention or a diagnostic / therapeutic procedure is efficient does not necessarily mean that it will lead to cost reduction; cost reduction and efficiency generally represent two different perspectives. Those diagnostic or therapeutic products which are more expensive than established alternatives - but which exhibit higher predictive value, greater effectiveness, more safety, fewer side-effects, etc. may be efficient.

Whereas private accounting is generally limited to factors measurable in monetary terms, classical economic analysis extends the examination to qualitative and intangible costs and consequences. It explicitly attempts to measure factors which are difficult to evaluate monetarily.

Costs, Costing Problems and Outcomes

The measurement of all effects of an intervention strategy in terms of cost and outcome components (benefit, results, consequences) is based on the distinction between the input of resources used by the intervention on the one hand, and its positive and negative outcome effects on the other.

Generally, the three categories of direct, indirect and intangible costs and consequences are differentiated.

Direct Costs: Direct costs are defined as the utilization of resources in the form of *goods* and *services*. This includes primarily the use of health care resources as pharmaceuticals, medical-technical services, lab work, medical consultation, hospital stays, etc. The consumption of resources in the individual patient's private sphere may also be included, such as transportation to and from health care institutions and special diet provisions.

Indirect Costs: Indirect costs are those associated with a *loss production due to sick leave*, *disability* or *premature death*. Such losses can occur in the production process (persons gainfully employed) as well as in every day household tasks (uncompensated employment; e.g. housewives).

Intangible Costs: Intangible (direct or indirect) costs are those that are incurred by patients and their families as a result of illness or intervention but which are not measured in money terms. Examples are *pain or grief levels associated with disability, morbidity or death.*

A fundamental difficulty in the assessment of costs is the absence of (meaningful) market prices for many health care goods and services. Generally, true market prices are available only for (some) direct cost and outcome components, due to third party payment. Thus potential 'cost saving' or savings of health insurance expenditures with a new medical intervention may not be savings to the society. As an example, consider 'average costing' methods (total direct and overhead costs divided by number of patients). If a hospital bed is freed by a new effective treatment that allows early discharge of patients, the hospital overhead cost per patient is not saved but increased. If no one else fills the vacant hospital bed, accounting would eventually have to raise the overhead charge to the remaining patients.

The results or consequences of a medical intervention can be called its medical and economic outcome. This includes changes in life expectancy and the state-of-health of a patient cohort or population.

The evaluation is based on a comparison of alternative treatments, including non-treatment. The medical benefits are measured by different parameters, within *life expectancy* and *quality of life* are most important. Other

medical outcome measures include progression of disease, patient compliance, frequency of complications and adverse events, etc.

The Methods of Economic Evaluation

In order to ensure the rational use of national income and resources, three basic types of evaluation were developed:

- Cost-benefit analysis,
- Cost-effectiveness analysis,
- Cost-utility analysis.

There are variations as well: Cost-Minimization Analysis, Cost-Consequence Analysis, and Cost-of-Illness Analysis. But their potential to support decision making effectively is rather limited. Quality-of-Life studies are very important to describe the burden of illness or – in case of an intervention – the improvement of quality of life from the patient's point of view (Table 1).

Table 1. Types of Study and Goals

Type of Study	Goal
Cost-Minimization Analysis	Determine *the least expensive* intervention strategy for accomplishing the same medical outcomes.
Cost-Effectiveness Analysis	Determine the *more efficient* intervention strategy for accomplishing the same type of medical results in terms of cost *per medical outcome measures* (cost per life years gained).
Cost-Utility Analysis	Determine the *more efficient* intervention strategy for accomplishing the same type of medical results in terms of cost *per constructed summarizing unit of outcome* (cost per Quality-Adjusted Life Years).
Cost-Benefit Analysis	Assessment in money terms of whether an intervention strategy is efficient, i.e. *worth doing*, and comparison with alternative intervention strategies to determine which is 'most' efficient.
Cost-Consequence Analysis	*Determine a listing of the medical and economic consequences* of alternative interventions - used to indicate their consequences without summarizing.
Cost-of-Illness	Determine of the cost of illness - used to indicate the need for treatment or the *potential economic benefits* from improved intervention strategies.
Quality-of-Life Study	Relative assessment of intervention strategies regarding *patient health outcome*. The health outcome is measured by disease specific health status parameters or general quality of life instruments.

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is a practical way of assessing the usefulness of public projects. In USA, CEA is required by law and regulation throughout the federal government to decide among certain alternative policies and projects. It has been recently required in federal regulations designed to protect human health, safety, or the environment.

Cost-effectiveness analysis is the process of using *theory*, *data* and *models* to examine both problem's relevant objectives and alternative means of achieving them. It is used to compare the costs, benefits, and risks of alternative solutions to a problem and to assist decision-makers in choosing among them.

Ultimately, CEA consists of methods for evaluating vectors of measures.

Cost-effectiveness analysis is not limited to only one specific outcome effect. An intervention-specific group of effects may be used, too. In general, the various medical outcome effects of a treatment cannot be summed up like cost figures. This aggregation necessitates complicated procedures and (potentially problematic) evaluations of the multiple outcome effects of interventions.

Cost-Benefit Analysis

In a Cost-Benefit Analysis (CBA) all elements - on the input side as well as on the output side - have to be measured in terms of money and/or converted to money where costs are not directly observable (value of a life).

The first CBA in health care was possibly conducted by Sir William Petty in London in 1667. He tried to show the impact of fighting against plague. He found out that 1 £ invested gained 84 £. The value of a life was calculated on the basis of a slave price (4).

At that time CBAs were primarily conducted from a *society's viewpoint*. Using this perspective we are interested to improve welfare of society. There have been a lot of discussions and theories how to define welfare and how to measure it. One important theory says that an alternative is better only when all the losers are compensated by the winners and there is still a net saving (potential Pareto-optimum).

We also have to keep in mind those beneficiaries and payers (investors) must not be the same. If we have a tax funded health care system (NHS) the societal viewpoint can be helpful. In the case of a contribution funded

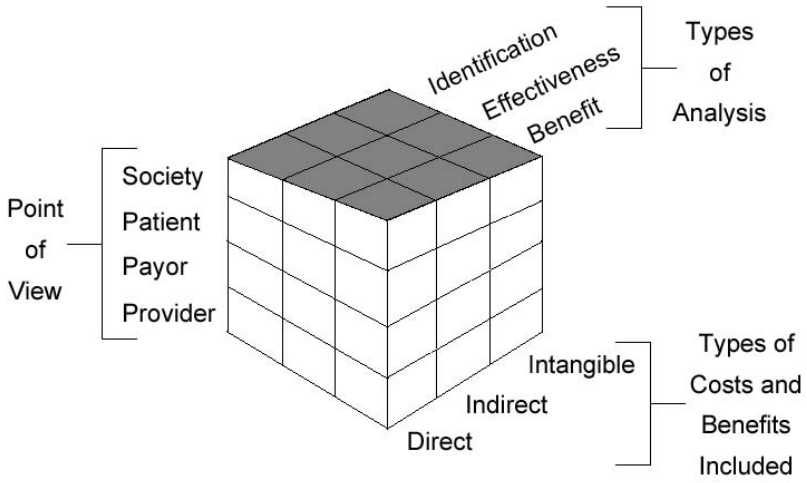
health care system, it's only the payer's perspective that really counts. The health insurance does not care for the pension funds problems.

Whether something is perceived as „useful", depends on the objectives and guiding principles of that person / institution who makes the evaluation / judgment are different. E.g. in Germany one day in the hospital costs between 17 DM (patient's view) and 600 DM (sickness fund's view).

Therefore, there is not one single form of CBA, it is rather a complex combination based on the perspective taken, and the cost elements included (Figure 2).

Cost-benefit analysis is not limited to one type of outcome effect. The results of the evaluation may be presented as an excess of benefits over costs or as an incremental ratio of benefits to costs (see decision rules). In the first case the result should be a positive number, in the latter case, it should be a number greater than 1. Otherwise costs would exceed benefits. With a cost-benefit analysis absolute efficiency can be measured.

Figure 2. Types of economic evaluation by type of analysis, viewpoint and effects included (5)



Source: Bombardier C and Eisenberg J (1984). in Glick H, Economic Analysis of Health Care, 2.21.03, Available from http://www.uphs.upenn.edu/dgimhsr/intec203.pdf

The weak spot of cost-benefit analysis is found in its intention to express all the outcome effects of a medical intervention in monetary terms. This forces evaluation of medical and social aspects, human life, quality of life, etc. in monetary units. The sphere of reference is the entire economy. Cost-benefit analysis requires the most comprehensive information and is therefore typically a very large-scale project.

Multi-dimensional analyses and cost-consequence of interventions which cannot be evaluated monetarily classify the outcome effects into medical, social and economic dimensions and register them by description only. There is no attempt made to aggregate all of the dimensions into one unit.

Quality of Life Analysis

Generally speaking, quality of life is a measure of the degree of satisfaction with living conditions. Here we refer to health-related quality of life (Figure 3). Quality of life is not an operational measure. It must be described in terms of relevant dimensions and measurement scales. The dimensions are defined according to the dimensions of health. The WHO in its 1948 definition describes health as the condition of 'total physical, psychological and social well-being and not as the lack of illness and frailty'. The three dimensions - physical activity, mental health and social interaction together form the nucleus of health - related quality of life. The quality of life analysis covers those input and outcome elements of a medical intervention which are relevant for the patient's ability to live a life unrestricted by health problems. 'Costs' are considered as far as they are reflected in the patient's quality of life (for example, an adverse effect on free-time activities, sexual life, ease of movement); 'benefits' are the advantages and improvements achieved within the same framework. Direct and indirect money costs are ignored. Consequently, such analyses are not economic evaluations in the sense of efficiency assessment.

The effects of treatments on the quality of life cannot be measured directly. Only partial dimensions and their respective indicators can be determined and measured directly. A generalized measure of quality of life which covers all health-related problems does not exist. Which dimensions of quality of life are relevant for which indications, and which mixture of standardized or disease specific instruments are used for measurement, depends on the clinical picture, and on the pragmatic limitations of the outcome study.

To select an appropriate measure of Quality of Life Analysis the following choices might have to be made:

1st choice: Standardized or non-standardised assessment: Quality of measurement outcomes and ease of interpretation

2nd choice: Comparison with outcomes of other diseases: Global measure, or disease specific measure needed? Age and/or sex specific? IQ requirements to be taken into account?

3rd choice: Acceptability: Instrument has been used in previous evaluations; Burden to the interviewee; Burden to the interviewer

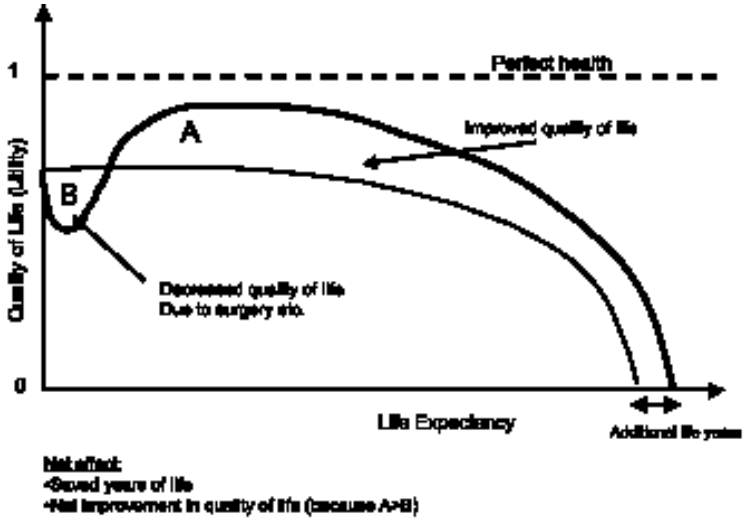
4th choice: Method of administration: Direct observation needed/possible; Face-to face interview; Telephone interview**;** Self-administered questionnaire

5th choice: Length and cost of administration

6th choice: Method of analysis and complexity of scoring

7th choice: Presentation of data and usefulness to decision-makers: Interpretation of data**;** Degree of certainty

Figure 3. The principle of quality adjusted life years



Unfortunately, there is a trade-off between comparability across diseases and the ability to detect even minor changes in different diseases. Depression might be very important in rheumatic arthritis and cancer but no that issue in the case of a broken leg and confinement to bed. Here the impact of reduced mobility would be more important. Standardized tools like SF 36 might not be first choice when we are aiming at detecting small changes.

An essential aspect of quality of life analysis is the fact that the evaluation of medical outcome effects are generally not derived from accepted medical endpoints (e.g. blood pressure) but made by the patient him/herself by self-assessment - a subjective view. These measurements are however supplemented in areas where the therapeutic progress is of a qualitative nature (i.e. suffering and/or pain relief, improvement in ease of movement, or subjective sense of well-being of the patient). The quality of life analysis identifies more efficient intervention strategies only if it measures the medical target and if costs are equal.

Cost-Utility Analysis

Utilities are measured for various possible health states. This can be done by asking patients who are in that particular health state at the time of measurement or by describing health states to subjects who may or may not have had personal experience of the health state being measured. The health state utility is a cardinal number, usually between 0 and 1.0, associated with a particular health state.

The conventional way of using these utilities is to convert them into quality-adjusted life-years (QALYs). This is done by multiplying the utility value by the years spent in that health state. For example, 10 years in a health state with a utility value of 0.5 would result in 5 QALYs (i.e. equivalent to 5 years of perfect health).

Balancing or weighting of target effects is needed; for example with respect to life expectancy and quality of life. There may be a trade-off, i.e. a higher life expectancy implies a lower quality of life. Cost-utility analysis determines the effects of alternative therapies for each target parameter, and then rates them according to the degree of preference on a dimensionless scale, e.g. an ordinal scale from 0 to 1. The effects of each intervention strategy are classified according to their importance, and then they are attached to a one-dimensional number standing for the level of utility.

A special type of utility analysis is widely accepted, in which utility is measured by quality-adjusted life-years (QALYs) gained. This outcome measure may be used in a multi-dimensional cost-effectiveness analysis, which looks into the changes in ‘life expectancy’ and ‘quality of life’ and costs involved. The final result of this analysis is a statement about the cost of gaining one additional quality-adjusted life-year through the use of a medical intervention.

Cost of Illness Study

Cost-of illness studies focus on the general costs of a disease to society. Such studies are valuable to indicate the burden of illness by measuring the extent of resources lost due to illness.

Decision Rules: How to determine Efficiency?

The goal of any health economics evaluation is to determine efficiency. We can look at efficiency from different perspectives:

- If it is impossible to make *any person better off without making someone else worse off,* an allocation of factors of production is *Pareto efficient*. That is from more holistic viewpoint.
- If the goods and services produced *exactly what consumers want*, an allocation of factors of production is *allocatively efficient*.
- If the goods and services are produced for the *lowest possible cost*, an allocation of resources is *productively efficient*. This is also referred to as technical efficiency.
- Product applications or intervention strategies which achieve a given health outcome at the *lowest level of resource utilization* are called *cost-efficient or economical*.
- Product applications or intervention strategies which generate the best possible outcome or goal achievement for a given resource input are called efficient or most productive. That is *output-efficiency*.

Most evaluations in outcomes research are done from the view of **productive efficiency.** Two fundamental options are available: ratios of costs and benefits, and differences, i.e. subtracting the cost from the benefits. By definition – because costs and benefits have to be both in monetary terms – the later can only be used in a cost-benefit analysis, only.

For decision-making purposes data have to be summarized in an appropriate way. There are several indices available that will provide condensed information. The choice of an index has to be guided by two questions, then:

- What question has to be answered?
    1. Would undertaking the project be better than doing nothing?
    2. Which of two mutually exclusive projects should be undertaken?
- What are the strength and weaknesses associated with the different indices?

Ad 1. In the case of comparing a project to the option of „doing nothing", cost-benefit analysis is the method of choice, displaying absolute efficiency.

Ad 2. Both CBA, CEA and CUA are applicable.

Table 1. Ratios of costs and benefits

Index	*Rules*
$\text{Gross\_BCR} := \frac{\sum \text{benefits}}{\sum \text{costs}}$	Cost and benefits are discounted when appropriate. An alternative with a higher BCR is more favourable • Gross_BCR > 1 The index is sensitive to enumeration of cost and benefits This ratio is applicable to a CEA or a CUA as well when benefits are measured in non-monetary terms, i.e. saved years of life, QoL An alternative with a higher Gross BCR is more favourable
$\text{Net\_BCR} := \frac{\sum (\text{benefits} - \text{costs})}{\sum \text{costs}}$	An alternative with a higher BCR is more favourable • Net_BCR > 0

Table 2. Differences of costs and benefits

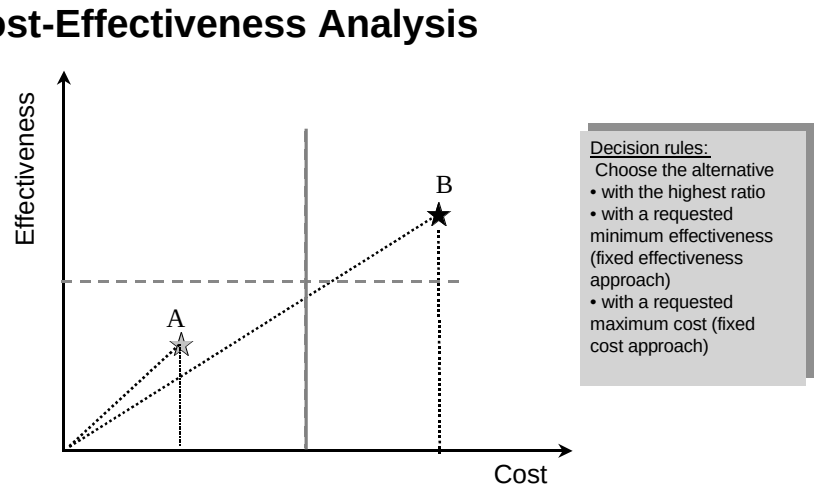
Index	*Rules*
$\text{Net\_benefit} := \sum (\text{benefits} - \text{costs})$	Cost and benefits are discounted when appropriate. An alternative with a higher positive net benefit is more favourable • Net_BCR > 0 An alternative with a higher net present value (NPV) is more favourable • NPV > 0
$\text{Net\_present\_value} := \sum_{i=0}^{n} \frac{(\text{benefits}_i - \text{costs}_i)}{(1+r)^n}$	r = discount rate, n = number of years

How to make choices

In a CBA both a ratio and a net benefit can be calculated. In a CEA or CUA ratios are applicable, only. Comparing two alternatives (A and B) the alternative with the biggest ratio (Gross BCR) should be chosen (see Figure 4). In this case A would be better because the tan(a) > tan(b). This might not be convincing in any case. Sometimes we might expect a *minimum effectiveness*,

which is marked by the horizontal line parallel to the cost axis, or a solution *within a budget limit* (blue line). When solutions are ruled out by setting a minimum threshold, this is called *fixed effectiveness approach*. Whereas ruling out by a budget limit is called *fixed cost approach*. This makes the rules more flexible. Nevertheless, economists prefer an even closer look. Sometimes it is important to understand what are the additional cost and the additional effects when comparing two alternatives. This is called incremental analysis.

Figure 4. Decision rules using cost-benefit, cost-effectiveness or cost-utility ratios



There are two notions: **incremental** and **marginal analysis.** These are no synonyms. Incremental analysis is the broader term and includes marginal analysis. Marginal analysis looks at the extra cost of extra effects in the same programme; incremental analysis looks at the differences between programmes. Decision based on average values (ratios) can be misleading.

A famous example shows the importance of a marginal analysis. Neuhauser and Lewicki (6) undertook a cost-effectiveness analysis (model calculation) to determine whether performing all six screening tests was a reasonable strategy. In the mid-1970s, the American Cancer Society recommended that, when attempting to detect cancer of the colon, each stool sample should be tested six times. Therefore, the first part of a sample would be tested. If the result were positive, the subject would go onto have further confirmatory tests and, if necessary, treatment. If the test were negative, the second part of the sample would be tested. If this tested positive, the subject would have further confirmatory testing and, if here, for ease of exposition): negative, the third part of their sample would be tested, and so on. A screened person would be confirmed as negative only after all six parts had tested so. Neuhauser and

Lewicki analyzed this policy based on the following (realistic) assumptions (simplified here, for ease of exposition):

(1) a population of 10,000 amongst which it is known (from epidemiological studies) that there are 72 cases of cancer;

(2) each test detects 91.67 percent of cases undetected by the previous test (The first test will, therefore, detect 91.67 percent of cases; the second test will detect 91.67 percent of the 8.33 percent of cases left undetected by the first test, and so on).

The authors estimated the cost of guaiac cards to be $4 for the first test and $1 for each subsequent test. Thus, as is shown in Table 3, about 66 of the 72 cases are detected after the first round of testing, the cost of this being US$1175 per case detected. The second round of testing ensures that almost all cases are detected at an average cost of US$1,507 per case detected. Six rounds of testing capture all cases at a cost of US$2,451 per case detected (Table 3 and Table 4).

Table 3. Cases detected, cost and cost-effectiveness of Guiac test (5)

No. of tests	Total cases detected	Total costs (USS)	Average costs (US$)
1	65.0465	77,511	1175
2	71.4424	107,690	1507
3	71.9003	130,199	1811
4	71.9385	148,116	2059
5	71.9417	163,141	2268
6	71.9420	176,331	2451

Table 4. Results from an incremental analysis of Guiac test (5)

No. of tests	Incremental cases detected	Incremental costs (US$)	Marginal costs (US$)
1	65.0465	77,511	1,175
2	5.4956	30,179	5,492
3	0.4580	22,509	49,150
4	0.0382	17,917	469,534
5	0.0032	15,024	4,724,695
6	0.0003	13,190	47,107,214

Source: Bombardier C and Eisenberg J (1984). in Glick H, Economic Analysis of Health Care, 2.21.03, Available from http://www.uphs.upenn.edu/dgimhsr/intec203.pdf

A more revealing way to look at the data, however, is in terms of the *extra* costs incurred and the *extra* cases detected by each successive round of testing, as in Table 2. Thus, two rounds of testing lead to extra 5.5 cases detected

compared with one round of testing at an extra cost of US$30,179, or US$5492 per extra case detected. Having six rounds of testing rather than five ads very little in terms of cases detected at an extra cost per extra case detected of over US$47million.

Discounting of cost and benefits

Alternative projects costs and benefits may occur at different points in time. Differences in the timing of costs and benefits are most obvious in preventive measures. An investment made today will yield most of its effects in the future. To make money flow comparable, the money has to be adjusted at one point in time – this is called calculating its present value. The process of transferring the values of any effect in one year to the corresponding values in a different year is called *discounting*.

There are two reasons why discounting is appropriate:

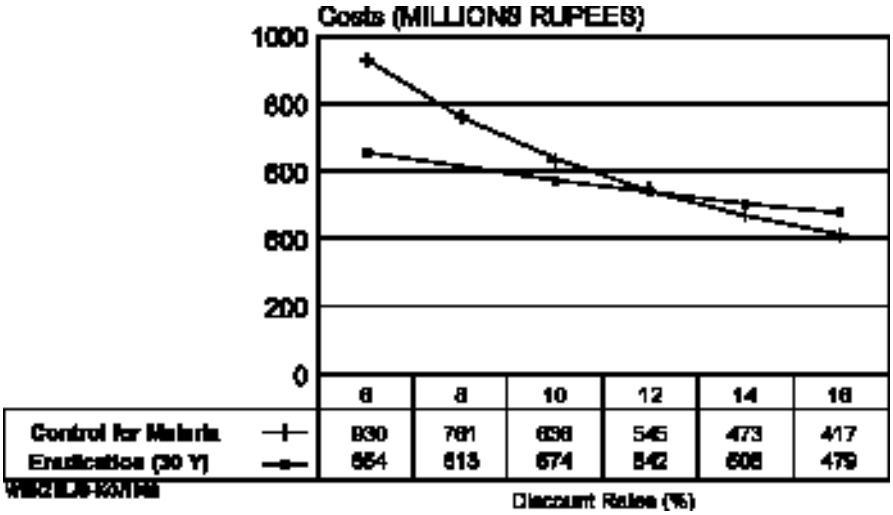
1. Marginal rate of time preference. People and authorities prefer benefits sooner than later and the reverse for costs. The strength of the time preference can be indicated by the size of the discount rate.

2. Opportunity cost of capital. To fund programmes, money has to be taken away from other uses (in case of a public programme, from the private sector). In the private sector the money could have been invested and produced benefits. The benefits lost are indicated by the size of the discount rate, then. The more productive the money would have been, the higher the rate (7).

A discount rate is a number relating the value of one year to the value in the next or previous year. Discount rates may often be thought of as interest rates. At a discount rate of 10% € 1 today is equivalent to € 1.1 next year or € 0.91 one year ago. The effect of discounting on the preferability of an alternative is very high (see Figure 5).

A comparison of two projects to fight malaria (8) showed that eradication seems to be less costly than controlling malaria. The ranking changes when the discount rate is higher than 12% (see Figure 5).

Figure 5. The effect of discount rate on the ranking of two projects (8)



Source: Cohn E, Assessing the Costs and Benefits of Anti-Malaria Programs, Public Health 63:1086, December 1973 and Amer. J. trop Med Hyg, 1972.

The lower the discount rate, the better are projects with benefits that are far in the future. Therefore the choice of the appropriate discount rate is an important issue and gives way to manipulation. To prevent manipulation by selecting a „useful" discount rate, governments of various countries have set discount rates for the evaluation of public investment projects. In the USA the rate for public investment projects is 10%, in the Netherlands 5%. This is based on the long-term rate of interest for government bond issues. In the various international guidelines on the economic evaluation of health services, the interest rates for discounting are usually set from 3 to 6%.

The only convincing way to control for manipulation is sensitivity analysis, where the effect of the discount rate on the outcomes and the ranking of alternatives are shown.

How to perform an Economic Appraisal?

As described above, health economics tries to answer the question by what criteria the worth of an object can be evaluated. How do we get the data needed for economic appraisal? Economic evaluation has to satisfy the scientific principles of unbiased research (9). Therefore all principles and methods of scientific research are applicable. There is no specific way of setting up scientific study designs - except the consideration of economic principles and the-

ories. Economic appraisal therefore benefits from developments in different research areas. In getting most useful data, techniques of experimental design are important. Statistical methods are needed to estimate program effects from diverse available data.

Once these and other disciplines in evaluation have yielded best estimates of program effects, the stage is set for cost-benefit analysis. Increasingly, program evaluators are not satisfied just to know that certain effects exist at specified levels of statistical significance. They also demand to know how various effects should be valued and how the different valued effects should be aggregated to facilitate program decisions. These decisions include:

(1) comparing all the good effects of programs (benefits) with all their bad effects (costs and dis-benefits) to judge whether it is better to implement or not to implement a program;

(2) determining which of alternative versions of programs are best; and

(3) deciding what collection of programs or projects constitutes the best expenditure within a set, overall budget limit.

These tasks are the main roles of cost-benefit analysis. Techniques of operations research and systems analysis may be invoked to ensure that the cost-benefit analysis is covering the full range of relevant alternatives. Organizational analysis and political science also play vital roles:

(1) helping to guide the appropriate assignment and aggregation of values for the cost-benefit analysis; and

(2) when the cost-benefit analysis is completed, applying it suitably within complex organizational and political structures" (10).

Stages in Economic Evaluation

Drummond (11) describes the process of planning an economic evaluation. He distinguishes three different areas that are connected by various interfaces.

- Area of technical appraisal - this is the description in terms of medical/technical criteria how a technique or product performes. It is the basis of the economic appraisal.
- Area of economic evaluation - this is the actual evaluation. It is divided into the following steps:

- deciding upon the study question,
- statement of alternatives to be appraised,
- assessment of costs and benefits of the alternatives,
- adjustment for timing and uncertainty,
- decision rules.

- Area of decision-making - this is the where decision criteria, alternatives to be appraised and timing issues are determined.

Those links are important. They make sure that the outcomes are relevant to the decision-maker.

The Research Question

The general objective of the evaluation study is expressed by the research question. A statement of the respective research question should be specified with respect to:

- the types of medical interventions or intervention strategies compared;
- the patient population considered;
- the range of medical resource inputs, clinical outcomes and economic consequences analyzed.

The Study Population

The study population should be representative for the population to whom the medical intervention strategy is applied in clinical practice, i.e. the target population. Depending on the intervention and its indication, this will be patients with a specific disease, stage or duration of disease or with a certain medical history, risk or symptom profile. Often cohorts defined by age and sexes are analyzed. In complex studies the population will be defined by combinations of characteristics or strata.

The effectiveness of an intervention strategy will often depend on how narrower the indication and the corresponding study population is defined.

The Study Perspective

In the field of health care there is a multitude of institutions and persons who are responsible for decisions concerning the availability and application of medical interventions.

The study perspective refers to the viewpoint from which the analysis is performed. Typically, four major viewpoints can be taken:

1. **Society**
2. **Third party payers** (government, health insurance, and health maintenance organizations)
3. **Health provider** (the hospital, physicians and other providers)
4. **Patients**

The perceptions of the study questions, the information needs and the evaluations differ according to each viewpoint. What is cost-effective for one target group (e.g. from a hospital point of view), may not be cost-effective for a third party payer. Costs and consequences that are extremely relevant to one target group may be ignored by another group.

For example the income of a health care provider is a cost to the health insurance, a benefit from one perspective is a cost from the other, and vice versa. The money costs of one day in hospital seen from the patient's perspective is his co-payment, whereas a health insurance perceives it's per day rate, and public hospital funding authorities see primarily their subsidies. The costs per hospital day to society may be more or less but will certainly be different. Each of these points of view will be examined below:

1. The Societal Perspective: From this viewpoint an evaluation would examine all social, medical and economic effects of a new medical technology on all parts of society. This means a wide array of health outcomes and economic consequences incurred in hospital care, outpatient care, long-term care, home care, nursing homes etc. regardless of when they incur or who pays for them. Moreover, a broad range of other ethical and social consequences might be examined.

New medical intervention strategies should be introduced and reimbursed if they improve social welfare. Not all new medical technologies warrant such a comprehensive assessment. Extremely expensive technologies, whose costs may shift relatively large amounts of resources from one area of the health sector to another, may justify such comprehensive study.

2. The Perspective of the Third Party Payer: Government agencies, public and private health insurance, and health maintenance organizations make decisions about the reimbursement or non-reimbursement of medical technologies. Therefore these institutions are a prime target group of economic evaluation studies. In study practice many studies are performed from the more limited perspective of the third party payer.

Often estimations of the annual budget impact are asked for. Information on the financial impact receives high attention especially in HMO and other managed care environments. Third party payers usually are not too much interested in indirect costs.

3. The Perspective of the Health Care Provider: The decision-makers on a micro level, such as physicians in outpatient care or hospital decision makers, often make their decisions under cost containment pressures and budget restrictions. Their perspective and information need generally concentrate on the impact of new intervention strategies on their budgets, and not on costs to other providers or to the society. The consequences of intervention strategies in other areas of the health care system are often ignored. For example savings in the outpatient sector may have unanticipated economic consequences in the hospital sector and vice versa. Generally the economic consequences of choosing medical intervention strategies on the national economy at large are often ignored. GPs or hospital decision makers generally do not regard indirect costs (losses or gains in production). The perception of a disease problem is rather focused on patient cases than population oriented.

4. The Patient's Perspective: From the viewpoint of the patient, costs that are not reimbursed and are out of pocket are most important. Costs borne by third party payers are widely ignored. For example, a co-payment for medication in out-patient treatment may represent higher out-of-pocket expenditures to the patient than fully reimbursed in-patient treatment.

The intervention related to quality of life is an important issue to patients, as well as the costs incurred due to the need for childcare or housekeeping help while receiving treatment. These costs have to be taken into account from the societal perspective too, but are ignored from other viewpoints.

Data Sources

Many times there is no chance to run a study quickly enough to answer the information needs of decision-makers. Most data are coming from secondary statistics and expert opinion, then. Health Economists are primarily interested to compare a new technology with the existing standard in an every day situation. Economic evaluation can be carried out on an empirical basis (primary research design) or on a modeling basis (secondary research design).

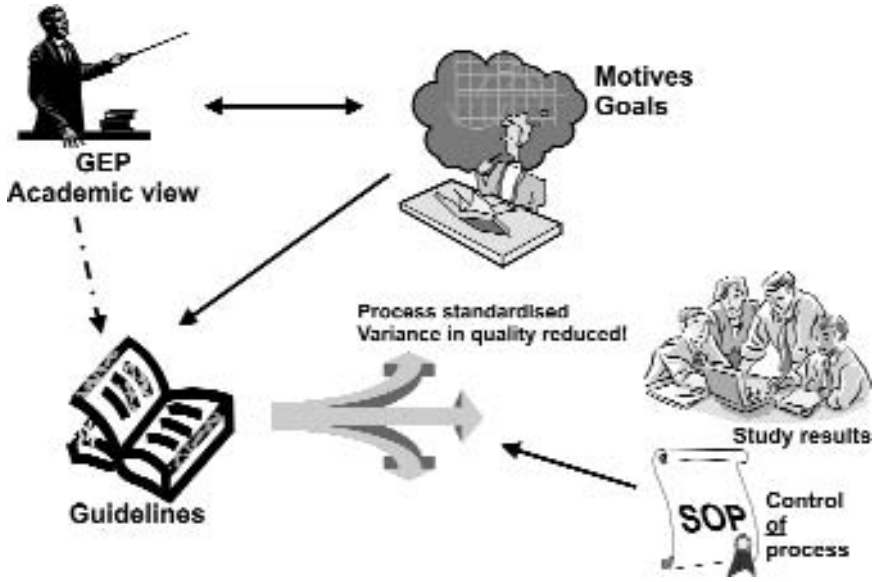
A highly appreciated design is a prospective study that proves effectiveness in a target population. This might be time consuming and costly, too. In specific situations where time for a follow-up would be very long, and data

of routine care are available, a retrospective cohort study might be appropriate as well.

Quality Assurance

At times where economic evaluations become more and more important, not only the underlying principles and theories are challenged but also the quality of studies is under debate. Figure 6 shows how different agents are working together.

Figure 6. The network of quality assurance



Academics believed in unbiased studies only when sponsors (industry mostly) had no influence on the designs and the publication of study results (thus preventing publication bias, when results are not positive).

At the same time representatives of governments and reimbursement authorities felt insecure and not well prepared to understand economic appraisal. This led to the development of guidelines (Australia was first), which goal was to create a kind of „cookbooks". As a consequence many things were regulated: the cost and benefits to be measured, the discounts rate, the quality of life measurement etc. Unfortunately, this might be contra-productive in a situation where a very new and innovative technique (drug, intervention, screening strategy) has to be evaluated.

Whereas the cookbooks (guidelines) tried to standardize the body of knowledge – instead of encouraging a proper education of evaluators – the standardizing of the process has a great impact on the quality delivered.

Aside of all the efforts to control the quality of both the body of knowledge and of the production processes, every reader or decision-maker can make his quality, check by following the checklist of Drummond. His „ten commandmends" of good appraisal practice suggest to judge the following items (12):

1. **Was a well-defined question posed in answerable form?** Did the study examine both costs and effects of the service(s) or programmes)? Did the study involve a comparison of alternatives? Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?

2. **Was a comprehensive description of the competing alternatives given? (i.e., can you tell who? did what? to whom? where? and how often?)** Were any important alternatives omitted? Was (Should) a *do-nothing* alternative (be) considered?

3. **Was there evidence that the programmes' effectiveness had been established?** Has this been done through a randomized, controlled clinical trial? If not, how strong was the evidence of effectiveness?

4. **Were all the important and relevant costs and consequences for each alternative identified?** Was the range wide enough for the research question at hand? Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third party payers. Other viewpoints may also be relevant depending upon the particular analysis). Were capital costs, as well as operating costs, included?

5. **Were costs and consequences measured accurately in appropriate physical units? (e.g., hours of nursing time, number of physician visits, lost workdays, gained life-years)**Were any of the identified items omitted from measurement? lf so, does this mean that they carried no weight in the subsequent analysis? Were there any special circumstances (e.g., joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?

6. **Were costs and consequences valued credibly?** Were the sources of all values clearly identified? (Possible sources include market values, patient or client preferences and views, policy-makers' views and health professionals' judgements). Were market values employed for

changes involving resources gained or depleted? Where market values were absent (e.g., volunteer labour), or market values did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values? Was the valuation of consequences appropriate for the question posed? (i.e., has the appropriate type or types of analysis – CEA, CBA, CUA – been selected?)

7. **Were costs and consequences adjusted for differential timing?** Were costs and consequences which occur in the future 'discounted' to their present values? Was any justification given for the discount rate used?

8. **Was an incremental analysis of costs and consequences of alternatives performed?** Were the additional (incremental) costs generated by one alternative over another compared to the additional effects, benefits or utilities generated?

9. **Was a sensitivity analysis performed?** Was justification provided for the ranges of values (for key study parameters) in the sensitivity analysis employed? Were study results sensitive to changes in the values (within the assumed range)?

10. **Did the presentation and discussion of study results include all issues of concern to users?** Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g., cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanic fashion? Were the results compared with those of others who have investigated the same question? Did the study discuss the generalizability of the results to other settings and patient/client groups? Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g., distribution of costs and consequences, or relevant ethical issues)? Did the study discuss issues of implementation, such as the feasibility of adopting the „preferred" programme given existing financial or other constraints, and whether any freed resources could be redeployed to other worthwhile programmes?

EXERCISE: Health Economics

Task 1: Health Care System and Efficiency

After introductory lecture students will participate in small groups in order to work out the goals of health care systems. The working process will follow a brainstorming approach using meta-plan-technique. Based on the existing permanent shortage of resources, possible options of managing health care systems according to the identified goals will be discussed. Advantages and disadvantages of the different solutions will be evaluated. Efficiency as a prerequisite for an appropriate health care system will be analysed thoroughly and described according to the theoretical background of economics. Each group will nominate a person who will present the results in a plenary session, then. In a final discussion the results will be evaluated by the teachers.

The assumed time span is about 1.5 hour.

Task 2: Economic Evaluation and Techniques

The work will continue again in small working groups (up to 5 students). In this exercise the key features of economic evaluation have to be deepened. Students will learn how the different evaluation techniques can be used best. Therefore the process of setting up an evaluation has to be studied, and depending on the study question, the appropriate outcomes, the proposed design and the evaluation technique have to be selected. Furthermore basic skills like discounting (and selecting the appropriate discount rate) and choosing a decision criterion have to be trained. To do so, financial and mathematical exercises have to be solved (calculated). Emphasis has to be laid on the understanding how the choice of a discount rate will eventually change the ranking order of efficient solutions and possibly prefer health effects in younger people.

For this exercise additional 3 hours are requested.

Task 3: Health Economic Publications

In this exercise students will learn how to judge the quality of health economic publications. Students will work in small groups and prepare a quality check of different publications of different quality that are delivered by the teachers. The result of the judgement will be presented in a plenary session and evaluated by the teachers. It is recommended to use the guidelines from M. Drummond.

This exercise requires 1.5 hour.

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Recommended reading

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Quality Improvement in Health Care and Public Health**
Module: 2.9	**ECTS (suggested): 0.25**
Author(s), degrees, institution(s)	Viktorija Cucic, MD, PhD, Professor Emeritus
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Keywords	Health system; health care; quality improvement; evidence-based medicine (health care); determinants of health; quality indicators; standards; criteria; practice quidelines; tools for quality; models; quality cycle; change, public health expert
Learning objectives	At the end of this topic, the students should be familiar with: • the difference between quality assurance and quality improvement approaches; • system approach to quality improvement; • key principles of quality improvement; • characteristics and roles of quality indicators, standards and practice guidelines; • tools and models of quality improvement; and • the importance of the role of public health expert in development and implementation of quality improvement policies, strategies and practical approaches at different settings.
Abstract	The specialization of public health and its role in developing and applying the quality improvement techniques is emphasized in this module. Quality is defined as a multi-dimensional phenomenon which demands specific organizational changes in order to be improved. The module explains the differences between the traditional quality assurance approach and quality improvement approach. It explains the basic principles for quality improvement, tools for quality, models and tasks for the public health experts.
Teaching methods	Teaching methods include: Lectures; Group discussion with topics What is quality of care, and What is the role of a public health expert in quality improvement; Visit to health care institutions and group discussion with staff; Seminars-Practice guidelines and the role of public health expert; Exercises-Which data can tell us something about quality. Practical experience with some tools for quality.
Specific recommendations for teacher	Stress the importance of specific skills that a public health expert needs to possess in order to contribute to the quality improvement in health care. It is recommended that the module will organize within 0.25 ECTS credits, out of which one third will be under teacher supervision, and the rest is individual data collecting and presentation preparing.
Assessment of students	Oral exam (the difference between quality assurance and quality improvement approaches, indicators, standards, tool, models, etc.).Written report on the health care quality characteristic of one health organization using EFQM model (need assessment).Written report about needed data for quality improvement policy at the local level or health care organizational level.

QUALITY IMPROVEMENT IN HEALTH CARE AND PUBLIC HEALTH

Viktorija Cucić

Quality improvement in health care is a worldwide trend and considerable efforts have been made both on national levels and on the international one.

Experts in almost all medical branches are seeking adequate definitions, methods and approaches to quality improvement in their respective fields in order to fulfill their professional obligations and satisfy in the best possible way the users-patients' expectations, as well as of all others concerned upon whom the quality depends. Public health experts have a twofold task in this respect.

On the one hand, they are obliged to develop adequate approaches for the quality improvement in their own sphere, and on the other, the development of those approaches represents in general a domain where a special engagement of public health professionals is expected. There is a various interest in the area of public health for the health care quality. Firstly, the overall philosophy of public health is based on health as a fundamental human right and obligation of the community to achieve it through common efforts. This includes interest in equal possibilities in health and health prevention, i.e., accessibility of health care of certain quality for all, disregarding any differences that may exist among people or territories.

Dealing in studies of health determinants, the public health also deals with health service and its influence upon improvement of health status of groups and overall population. Next, the role of public health is «to contribute to health of the public through assessment of health needs policy formulation and assurance of the availability of services» (1).

Availability of services can also be understood as availability of effective, eficient, acceptable, accessible and relevant health services. These are in fact dimensions of a health care quality, as recognized by one of the quality theoreticians Maxwell (2).

The new public health strategy, adopted in 2002 by the European Union, promote and bring together activities in the Member States in the fields of evidence-based medicine, quality assurance and improvement, appropriateness of interventions, and health technology assessment (3).

Finally, in reviewing the reasons mentioned in literature as those requiring the activities aimed at quality improvement, one can conclude that a detailed analysis of those reasons, their documentation and measurement is in fact in the domain of a public health specialist. Thus, referring to the European Union, Swow mentions the following reasons (4):

- Unsafe health system;
- Unacceptable levels of variations in performance, practice and outcomes;
- Ineffective or inefficient health care technologies;
- Users dissatisfaction;
- Unequal access to healthcare services;
- Waiting lists;
- Unaffordable costs to society;
- Waste from poor quality.

The position and role of the health care service as a health determinant is mentioned with much controversy and extreme views. On the one hand is a radically negative approach founded by McKeown (5) and Ilich (6) who point out that the role of health service in achieving the health improvement is minimal, and that all changes accomplished in improving the health of population were actually conditioned by changes in other determinants which are predominantly social and economic, not as influenced by the health service. On the other hand, we have an approach which could be called strictly medical, in which a better health condition is directly linked to the development of a specialized health service along with the use of high technology.

Without diminish the influence of numerous other determinants, somewhere in between these two views are those who claim that «Health care itself (is) an important and often underestimated determinant of health« (7). Certain researches prove such reasoning.

Thus the research published by the National Institute for Health 1990 suggest that, from the viewpoint of the contribution to the health status of a population, the healthcare services and interventions actually differ in as much as they are or are not evidence-based. Analysing the services in the USA (8), only 21% of all diagnostic and therapeutic services are evidence-based. Contrary to this, analysing the surgery services states that these are evidence-based in 95 % cases (9).

The literature also presents numerous proofs which point to the positive influence that the multitude of primary and secondary prevention programmes have onto the improvement of health status and prolongation of life, indicating that early detection and treatment of disease gain significant survival and quality of life outcomes (e.g., screening for cervical cancer, immunisation programmes, HIV therapy, and so on).

One can thus safely state that the contribution of the health service to the health status is all the more evident as it is of better quality.

The quality health care is the one which is (10):

- Doing the right things (WHAT)
- To the right people (TO WHOM)
- At the right time (WHEN), and
- Doing right things right first time

Development of quality concept

There is much knowledge gathered on quality in health care and methods of its improvement. Rich literature evidences the long and persistent quest for objective assessments in this very complex sphere, the functioning of which depends on numerous different partners.

We have travelled a long way from the traditional approach such as quality assurance to the modern one, such as the Total Quality Management (TQM), which includes, according to Uehara (11):

- Quality control cycles (QC),
- Continuous Quality Improvement (CQI),
- Evidence-based medicine,
- Critical Pathways,
- Practice guidelines,
- Customer Satisfaction Surveys, and
- Performance indicators.

Along the way the philosophy, concepts and methods have been changing and it seems that the process is not completed yet.

Indicators, standards, criteria, guidelines

The development of methods and tools to measure quality and performance in health care seems to be a fundamental component of improving quality in health care.

Search for the **«quality indicators»** is a common request by all those interested in any way for the quality, from investors, policy makers, managers, professionals, to public opinion. The indicator is expected to have »ability«, to indicate problems in health care which have to be solved by various quality improvement methods.

There are numberless definitions of indicators. So, JACHO (12) defines it as »a measure used to determine in a period of time whether the functions of the process and outcome were performed«. While Mc Glynn wrote: »An indicator is a measurable item of care which focuses upon some aspects of structure, process or outcome« (13).

There are various types of indicators:

- Activity indicators – measure the frequency with which an event occurred (e.g., children immunisation), and
- Performance indicators, which should serve in formulating the appraisal of the prevention process.

Indicators may be defined for different levels, form the national to the level of a particular health institution. However, each country has to develop its own indicators.

»It appears that indicators developed for health system in one country should not be transferred directly to another country, but it is possible to use indicators from other country as a starting point to produce own indicators« (14).

Today it is important to use High Level Performance Indicators (15), which are presented below:

Health Improvement Indicators:

- Standardised all cause mortality ratio (aged 15-64),
- Deaths from all circulatory diseases,
- Suicide rates.

Fair Access to Care Indicators:

- Surgery rates, composite, consisting of age standardised elective rates for:
  - Coronary artery bypass grafts,
  - Hip replacement (age 65 or over),
  - Knee replacement,
  - Cataract replacement,
- Size of inpatient waiting list per head of population.

Efficiency Indicators:

- Case mixed adjusted length of stay.

Effective delivery of appropriate health care:

- Early detection of cancer, composite, consisting of:
  - % of target population screened for breast cancer,
  - % of target population screened for cervical cancer,
- Mental health in Primary health care
  - Volume of benzodiazepines.

Health outcome indicators:

- Contraception below 16 aged,
- Decayed, missing and filled teeth in five year olds, average number,
- Adverse events – complications of treatment,
- Infant mortality rate,
- Potentially avoidable mortality (from peptic ulcer, fracture of skull, asthma etc.),
- In hospital premature deaths (30 days preoperative mortality rate; 30 days mortality rate following myocardial infarction).

There are many benefits of using quality indicators. The most frequent are (14):

- Allow comparison to be made between practices, over time or against standards,

- Facilitate an objective evaluation of quality improvement initiative,
- Can identify unacceptable performance, and
- Stimulate informed debate about quality of care.

Indicators are usually followed by development of criterion of care.

The literature defines it in different ways, but generally they refer to »expected level of achievement in regards to which measures of performance and quality can be compared« (12). Standard is «the level of compliance with a criterion or indicators».

Practice Guidelines have a particular role in improving the quality and activities concerning their development are ongoing in many spheres. They are defined as: »Systematically developed statements to assist practitioner and patient decisions prospectively for specific clinical circumstances, in essence the 'right things to do'« (14).

Tools for quality improvement

The most notable developmental change in the philosophy of quality in health is shifting the focus of «responsibility» for the quality and emphasizing an almost exclusive responsibility of an individual professional (meaning a physician) from the importance of structural characteristics for the good quality onto the organizational characteristics of the whole health system and the health institutions in particular, as well as to the strong leadership. At the same time, there was a shift from the «control from above» onto the organizational changes which provide conditions for the better quality. In order to get more familiar with and analyse the organizational system characteristics, and in order to describe and depict those characteristics, and with the purpose of proposing solutions for the correction of detected problems it was necessary to create or adopt special tools.

One of the tools for quality improvement is the use of a statistical method for collecting, processing and graphic presentation of data on various phases of the constant improvement of quality. Wilson classified these according to the purpose they are used for as those serving to (16):

- present data on organization (Histogram, Check Sheet)
- analyse data (Pareto Diagram)
- note and present convictions or opinions (Fishbone Diagram or Cause and effect diagram)

Application of those Tools, according to some authors, can solve 95 % of organizational problems and in that way improve the quality in any organization, including the healthcare one (17).

Strategies and models

Strategies, i.e., methodological approaches in improving the quality are abundant in literature, each one following the experience gained in applying it. There are numberless classifications, systematizations, divisions of those steps. One of the latest to be published by Overtveit, speaking about ensuring quality in hospitals, mentions the following strategies (18):

- Increasing resources;
- Large-scale reorganization or financial reform;
- Strengthening management;
- Development of standards and guidelines;
- Patient empowerment and their rights;
- Quality management system;
- Quality assessment and accreditation, internal and external;
- Total Quality management (TQM) and Continuous Quality Improvement (CQI);
- Quality collaboratives;
- Re - engineering;
- Quality indicator comparison;
- Benchmarking; and
- Risk Management and safety.

A more detailed analysis of these strategies goes beyond the scope of this module, all the more so as the publication clearly states that there is not a single approach, not one strategy that could be separated from the others according to its efficiency and influence onto the improvement of quality, or any of these could be recommended universally.

Generally, it is pointed out that there are very few systematic, evidence-based researches which could show how much a strategy or a methodological approach is really effective in improving the quality on a macro-level or on the level of a health institution. There is no evidence to corroborate the claims that certain noted changes are truly the result of a strategy being applied and not for some other reason.

Editorial «Quality and Safety in Health Care» Journal states:

»From what we know, no quality improvement programme is superior and real sustainable improvement might require implementation of some aspects of several approaches – perhaps together, perhaps consecutively. We just do not know which to use, when to use them or what to expect« (19).

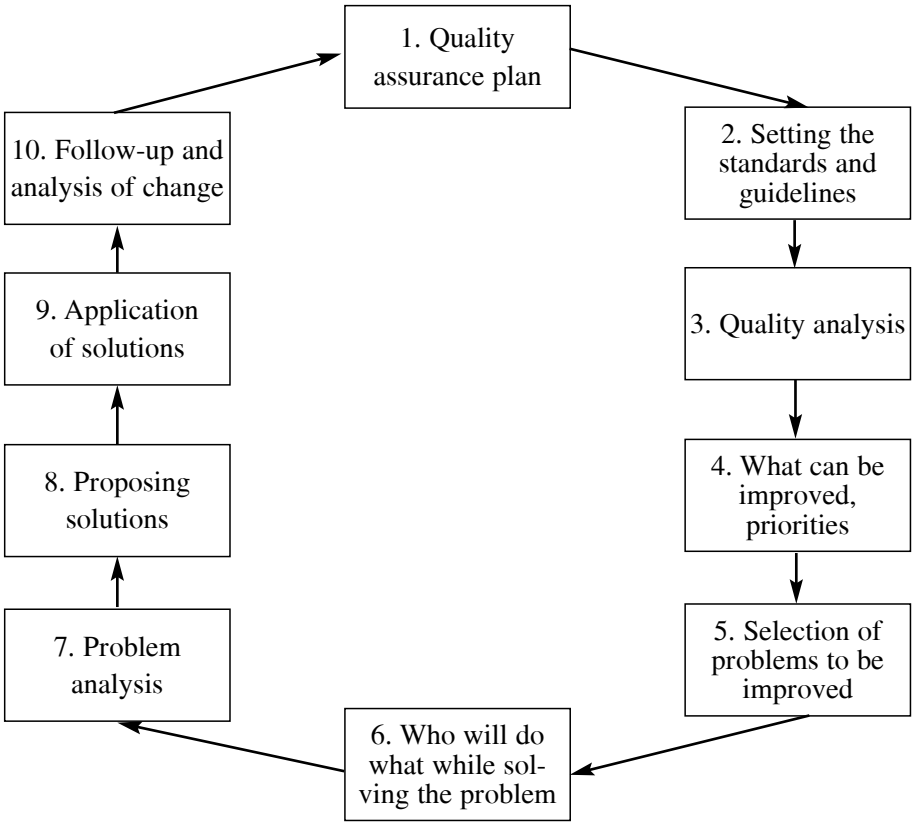
The literature, however, stresses that application of multiple strategies gives better results in improving quality. It actually means that combining several strategies offers better prospects for success than using a single one.

Such undertakings of combining a larger number of strategies can be found in models for quality improvement.

Models for quality improvement have also changed and developed the philosophy of quality assurance toward a philosophy of quality improvement, i.e., from »systematic cyclic activity where quality is measured and standards are used» to »continual activities in improving«.

The model of a «Cycle» belongs to the phase of quality assurance:

Figure 1. Quality assurance Cycle (20)



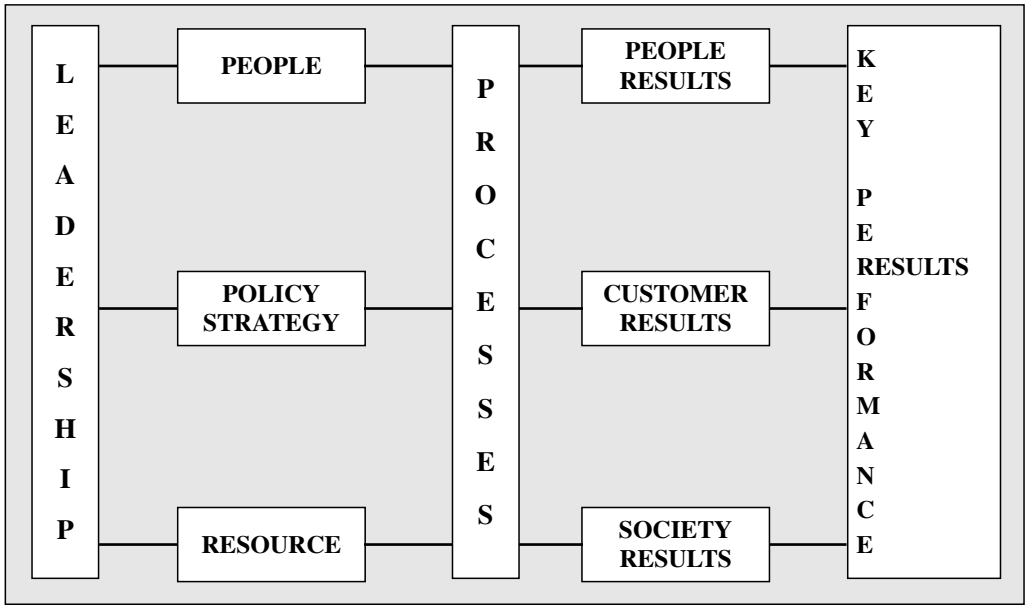
This systematic approach identifies the problems by one or another form of internal or external peer review, different activities in overcoming the problem, and initiates corrective activities in order to avoid the similar problems.

The model known as RAF (Regulation, Assessment, Follow Up), developed in the 80's and adapted several times since then represents a shift from quality assurance approach to the continuous improvement of quality (21).

The model integrates three theoretical approaches to create broad conceptual framework. Those are: Tracer Approach, quality assurance and organizational changes. Organizational changes are essential for further models of Quality management which involve at least the following entities (22):

- Resources,
- Activities,
- Patients, and
- Outcome or effects.

Probably the best known is the conceptual quality model - The European Foundation for Quality Management - EFQM, or excellence model (European Foundation for Quality Management, 1999):



The model is based on nine components. Analysis of each component at any decision-making level offers a possibility to determine reasons for good or bad quality and basis for suggesting the measures for its improvement.

If adequate answers are given to some of the questions asked in this text we could acquire a clear picture of the quality and everything needed to be done in the organization or at national level in order to improve the quality.

1. Leadership

It is important to learn:

- How does the leadership (from national, regional authority to specific programmes or health care organization) demonstrates its involvement in quality management and improvement;
- How does the leadership support activities directed towards quality management and improvement;
- How does the leadership recognise and award improvement.

2. Policy and strategy

- How are policy and strategy being developed and implemented in practice (based on relevant information or not);
- How are policy and strategy being communicated;
- How are policy and strategy being evaluated and changed.

3. People

The most important «people« are staff, or all individuals employed in the organization, programme or system being described:

- Is there any human recourses strategy;
- How are skills and capabilities of staff being developed and preserved;
- How is the involvement of all staff in quality improvement being promoted.

4. Resources

Beside human resources there are others necessary for the quality. A detailed analysis is needed. These are: financial resources; information; suppliers, material, buildings, equipment; application of technology.

5. Processes

Identification of main processes which influence quality is a complex task. Primary processes relate to the procedures directly connected with providing health care. Those are patient care activities (examination, treatment, discharge, follow up) but also patient information, infection prevention, safety, ethical issues.

Support processes are necessary for functioning of primary processes. Examples include: administration, procurement, cleaning, catering, ect:

- How are critical or primary processes being identified;
- How are processes being managed, evaluated and improved;
- How are innovation and creativity being stimulated; and
- How is process change being implemented.

6. Customer results

Here we first have to define who the customers are, what each group expects from a health institution, and then to analyse achievements regarding these.

Customers can be: patients / consumers (healthy people, people in care); other care providers (partners); providers of services or goods, financiers, etc.

Different assessment methods for the measurement of satisfaction are usually applied, directly or indirectly.

7. People results

As was stated, this refers to the staff and the achievements in relation to staff satisfaction.

This satisfaction can also be assessed:

- indirectly, when absenteeisam, sick-leaves, percentage of people leaving organization, accidents, complaints, readiness for doing extra work, are being measured
- directly, by one of structural methods for assessing satisfaction.

8. Society result

What is organization's contribution to the society or community at large. Are there any legal or some other impediments which obstructed the contribution of a health institution in a community where it is situated. What are facilitating factors enabling the contribution.

9. Key performance results

Here it is necessary to describe all the results that should have been realized according to the plan. It is also necessary to compare results achieved in a given situation or level with other results, predefined indicators, standards and criteria.

It is necessary to answer:

- What is achieved in relation to service objectives and in satisfying the needs and expectations of different stakeholders.
- What are financial results and operational results.

Operational results are:

- Productivity (admissions, services, length of stay, bed–days),
- Effectiveness / non-effective actions (effective care, compared to indicators, non planned readmissions, infections, complications, incidences),
- Efficiency / non efficient actions (staff working hours; time per consultation / procedures, waiting time; cancellations, wrong tests, procedures, unnecessary procedures etc.),
- Other treatment results.

ISO model, which is also used in health systems, involves all the entities mentioned in EFMQ model and some additional areas (23):

- Management,
- Measurement,
- Analysis, and
- Ongoing improvement.

The literature states other models as well which are used to improve quality, along with numerous experiences in applying certain models, but there are quite few researches to prove that application of those models contributes to some lasting changes in the organization. Overtveit (24) states that two studies offered clear-cut evidence that TQM approach applied in certain period of time brings an improvement of quality, but that the repeated evaluation, after two years, shows a regression to the former state.

Current state of art in quality improvement and the role of public health professionals

Diversity, a great number of possibilities and options for research and practical application of models and methods for improving the quality – are the main characteristic of the present state in this field.

Experts agree that there is a very small possibility that any health system in any community would be able to secure the quality of health care in all its dimensions as defined by Maxwell (2) and later by IOM (14). Experts also admit that there is no strategy to be designated the best and universally recommendable.

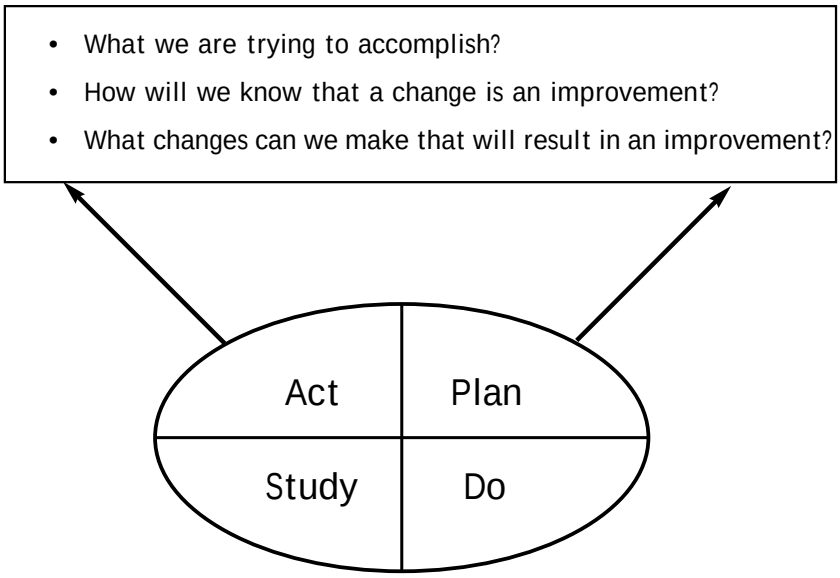
There are, however, proofs «that some quality methods can be used to increase efficiency and reduce harm to patient« (24). It is also pointed out that there is no possibility to transfer (copy) the policy, strategy or practice of quality improvement from one country to another. Each of these components, though based on identical common principles, must carry clear local characteristics and features. These are challenges defining the surroundings in which a public health expert works.

To understand how health care quality can be improved it is essential for public health professional to have a framework of the dimensions of health care around which quality can be assessed and improved. A public health expert is expected to get acquainted and to adopt the three key principles of quality improvement (25):

- Improving the quality of health care implies **change;**
- Health care quality is **multi-dimensional**;
- Health care quality is a product of **individuals working with right attitudes in the right systems and organizations.**

A public health expert is also expected to have a series of skills needed for the work in this field, such as need assessment skills, critical appraisal, application of evidence-based health care, management skills etc. Development of the system approach is also particularly important. Model PDSA or Plan - Do - Study - Act can offer answers to many important questions in the process of quality improvement (26,12,25):

Figure 2. Framework for improving the system (25)



Besides, possessing the team-work skills, particularly for working with clinicians, is one of the most important skills that a public health specialist should possess and upgrade.

EXERCISE: Quality Improvement in Health Care and Public Health

Task 1: Variations in medical practice

Variations in medical practice are one of the most frequently mentioned reasons for the development and application of quality improvement mechanisms.

With whatever sort of data we may gather in medical institutions (for example, the average length of treatment for the single diagnostic entity, mortality referring to the same disease at certain age groups, percentage of hospital beds occupancy, and so on) we shall notice that those vary considerably from one to another medical institution.

Perceiving and analysing these variations search for their causes are parts of the quality analysis process. Frequency histogram is used as a tool for graphic presentation of variations.

Students will have assignments to collect data at three general hospitals' surgical wards on:

- time interval from admission to OR for elective surgery,
- number of analyses and examinations performed upon each patient prior to operation.

(The collected data above are to be presented by a frequency histogram (two) and the noticed differences are to be discussed).

- collect data on Caesarean section rate as per regions in the country and number of obstetricians–gynaecologists in the same regions.

(Present data graphically, and then discuss the results).

Task 2: Global indicators

Wilson (16): «Because the delivery of health services is complex and has multiple goals no single measure is apt to capture overall quality. Still everyone would like to have a universal quality meter that readily generates for each provider an overall score that is both valid and meaningful».

Students should collect data in several hospital around the country for the calculation of the following indicators, calculate the indicators and compare them in small and big group:

- Surgical in-patient cancellation rate,
- In-patient autopsy rate,

- Adult death rate,
- Postoperative death rate < 48 h,
- Hospital complication rate,
- Unplanned returns to Intensive (or Special) care unit,
- No. of medical incidents,
- Surgical wound infection rate.

Collective work: choose, define, and explain some of the oncology care indicators (examples for the solutions):

- Screening mammography, women age 50-69,
- Pap Smears, women age 18-69, and
- Quitting Smoking, both sexes.

Collective work: choose, define, and explain some of the public health indicators (examples for the solutions):

- Immunization rate,
- Birth rate,
- Infant mortality rate,
- Mortality under 5,
- Mortality rate,
- Changes in self-reported health status,
- Changes in functional independence measures,
- Client satisfaction with health services, and
- Changes in health-related knowledge, attitudes, skills.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Accreditation of Health Institutions as an External Tool for Quality Improvement**
Module: 2.10	**ECTS (suggested): 0.50**
Author(s), degrees, institution(s)	Vesna Bjegovic, MD, MSc, PhD Snezana Simic, MD, MSc, PhD Both authors are professors at the School of Medicine, University of Belgrade, Serbia and Montenegro
Address for Correspondence	Insitute of Social Medicine, School of Medicine, Belgrade University Dr Subotića 15, 11 000 Belgrade Serbia and Montenegro Tel: +381 11 643 830 Fax: + 381 11 659 533 E-mail: bjegov@EUnet.yu
Keywords	Accreditation, quality assessment, visitation, standards
Learning objectives	After completing this module students and public health professionals should have: • increased their understanding of external tools for quality improvement; • identified key four models for external quality assessment; • explored the similarities and differences between existing mechanisms; • improved their knowledge in accreditation procedure and international projects, which support national accreditation; and • understood the main trends influencing the process of external assessment as a part of continuous quality improvement in health care.
Abstract	The main model of external quality assessment and improvement were developed particularly in the last two decades of the twentieth century. Among them ISO certification and EFQM model are based on industrial concepts applied to health care, while visitation and accreditation were developed within the health care system itself. Today many countries are interested in the process of accreditation as the systematic assessment of health institutions, which is based upon external peer review system and involve written standards. With growing interest in accreditation, the procedure for establishing accreditation bodies was simplified, and those bodies get international expert help for their development and in developing the national standards and services. An example of such help is ALPHA programme, which is founded within ISQua (International Society for Quality in Health Care).
Teaching methods	After introductory lecture students will participate in nominal group technique in order to recognize and to rank the field in the quality of health care where organizational, managerial, or other improvements are necessary, such as waiting lists, admission policy, medical records keeping, patient's discharge procedure, administration of drugs, working in multidisciplinary teams, patient satisfaction, etc. Then they will work in small groups, divided according to country or working place, to discuss the possibilities for improvement in their own environment. The second exercise will be to discuss, within the country (or working place) small groups, the necessary procedure for development of national accreditation system. Teacher will advise them to follow existing models and experience and to highlight their advantages and obstacles in the case of application within the country of SEE region.

Specific recommendations for teacher	It is recommended that the module will organize within 0.50 ECTS credits, out of which one third will be under the teacher supervision. Teacher should be familiar with Internet resources, where necessary evidence of well-established accreditation could be obtained. Teacher should also be ready to help students to explore the website of International Society for Quality in Health Care as well as the website of Joint Commission on Accreditation of Hospitals.
Assessment of students	Multiple choice questionnaire and written design of national accreditation procedure.

ACCREDITATION OF HEALTH INSTITUTIONS AS AN EXTERNAL TOOL FOR QUALITY IMPROVEMENT

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Examples from many countries around the world point to a growing movement aimed at continuous quality improvement in health institutions, and many authors call it a »quality revolution« (1). Endeavours to provide the quality are an inseparable part of the health reforms, the dominant part of which are efforts made to increase efficiency and effectiveness, while keeping a certain level of equity in the health services provision (2,3).

In the light of those strivings, the external tools for quality improvement in health institutions have their special place, while concern for their development is motivated differently in conformity to different stakeholders in the health system (4,5). Thus, when it concerns the government, the external models of health care quality assessment are seen as new control mechanisms which would guarantee not only the quality of health sevices, but also higher responsibility and transparency which are neccessary for a more efficient system worth trusting. Health professionals view the external tools of quality assurance from another perspective. Their interest lies in increasing the efficiency of certain health institutions, in realizing the competitive advantages under the conditions of a controlled market, and in an outer incentive for further development of the internal quality system. The health professionals always wonder if various models of external quality assessment would limit their clinical freedom, and whether the health professionals would be under extreme control due to developing and applying of these models. When it refers to patients, although their position is improving in many European countries, their influence over the external quality assurance programmes is still limited. The patients' main focus is on transparency and their higher participation in the health system decision making, based on adequate information on the quality of work. The main interest of the investors, regarding the application of external mechanisms, is in preserving the balance between the higher investments in administrative activities whose cost-effectiveness is not known and their inclination to contract services with particular suppliers under the conditions of a controlled health system market.

The quality improvement movement and the external quality assessment are both extremely actual in health systems around the world. Governments, users, health professionals, managers and financiers are all trying to establish new external mechanisms in order to institute public responsibility, transparency, self-regulation, improvement of quality, and adequate »value for the invested money« (6).

In an ideal situation the external tools for the improvement of organization and provision of health care are based upon (7):

- explicite, valid standards,
- reliable quality assessment processes, and
- complementary mechanisms applied for improvement.

Standards are related to the level of excellence, they serve as basis for comparison, they represent a minimum to which a community is to pay attention, and are recommended as models to be emulated. Standard of quality is a statement that defines expected performance, structure, or processes which must be present in a health organization if it is improve the quality of care (8). The process of quality assessment includes measurement or following of the function of secured quality so that it could be determined how well is the health care provided as compared to applicable standards or allowed limitations of health care (9). It is a process of establishing and measuring the differences between efficiency and effectiveness that can be ascribed to the health care, which is offered, including the variations among regions as well as among people. In a practical sense, it is the measurement of technical and interpersonal aspects of medical (health) care (10). Explicite identification of spheres where improvement is in place, as based upon proofs found in the assessment – reaching the standards is a strong incentive for participation of all partners in the implementation of changes that lead to improvement (11).

Acceptance of any form of external quality system in health care is closely connected to the social, economic, and political climate of a country which is determining the advantages and obstacles for those activities. It is assumed that the external quality assessment mechanisms are introduced and developed in European countries in a context characterised by (2):

- covergence of the Bismarck and Beverage models of health care system financing;
- government policy based on deregulation, decentralization, and self-regulation, together with strengthening the role of the patient;

- responsibility mechanisms as the creation of a new balance between trust and control among various partners in health care;
- the economic and industrial way of thinking is dominant in development of those models;
- application of the public-private mixture of health service providers and their financiers with public-private agencies, mostly of non-profit orientation.

In a situation where some countries have comprehensive legislation related to the quality management in health care, and where other countries have only regulations referring to certain special mechanisms, it is only understandable that models of external quality improvement vary from country to country (12).

Models of external tools for quality improvement in health care system

Modern analyses show that the external tools for quality improvement were developed particularly in the last two decades of the twentieth century, and that four models can be identified most often. The first two of those are based on industrial concepts applied in health care, and the last two models were developed within the health care system itself (2,13,14):

1. ISO certification (Certification by the International Standardization Organization),
2. EFQM model (Model of the European Foundation for Quality Management),
3. Visitation programme, and
4. Accreditation.

1. ISO model

The model was created by the International Standardization Organization while developing standards for the quality systems – ISO 9000. As the standards refer to the administrative procedures and not to clinical results, inside the health system they are mostly used in more technical departments and wards, such as laboratory, radiology, and transportation, but sometimes they are applied onto a whole hospital or clinic. The model is particularly utilized in Germany and Switzerland (6). By the ISO model, the national board

for the quality in health care tests and recognizes an independent agency as competent to certify those organizations which adhere to these standards. The verification process tests the adherence to the standards and it is not directed at organizational development. Anyhow, the ISO 9000 series is a collection of five separate but interconnected international standards for quality management and quality assurance (15). Revised version ISO 9000: 2000 represents an improvement as they were set up by using a simple structure based on the process. The basic units of the revised standards are responsibility of the administration, resource management, process management, measurement, analyses, and process improvement.

The verification in the ISO model is done by experts for ISO norms, not by experts for a special type of organization, so that it is not a form of peer review (2). Certification, as process of recognizing the fulfillment of certain preset standards, refers to the system of quality, not to the actual contents of work. As applied in the health care, this model helps in orientation onto the process, but it does not guarantee that the selected treatment is adequate, nor does it refer to the health outcome. Basically, this model does not affect the clinical process, but only the managerial one within which the clinical decisions are made. Therefore, the ISO standards are easily applied by health institutions' technical departments. Unfortunately, the limitations are not always recognized by those outside the health sector (financiers, patients) so that they sometimes advocate strongly for the introduction of the ISO model in the health sector.

After its initial application and after the limitations were recognized, there appeared »anti-ISO« movements in some countries, Germany in particular. Still, some countries, like the Netherlands and Switzerland, found ways to integrate the model into approaches which are more specific for health care, such as accreditation.

2. EFQM model

The model was designed by the European Foundation for Quality Management, founded in 1988, with over 600 organizations throughout Europe involved in its work. The EFQM model is based on »business excellence«, and was initiated by Malcolm Baldrige's model of »excellence« in the USA. It stimulates organizations and helps them improve those activities which lead to excellence in satisfying the users, to professional satisfaction, and to the improvement of management in general. It bolsters the implementation of management through total quality (14).

This model's instruments are schemes of rewards (European and world schemes), as well as publication of models which may be used in self-evaluation. It is considered to be the most complicated organizational model designed to fulfill certain objetives referring to total quality management (2). However, this is still a general model, not adapted to activities such as health care. Still, its attributes, such as high validity, experimentation with self-evaluation of the work quality, its simplicity and compatibility with the structure-process-outcome approach make it rather popular with health systems of West Europe, particularly in Scandinavia. It is especially popular among the managers of health institutions. Also, the use of self-evaluation can be considered as a certain form of peer review, where all the members of an organization are regarded as colleagues. The expenses in this model are relatively low, and there are some elements of positive competition, especially if the organization wins a citation.

A weak point of this model is that, beside conferring rewards for recognized good quality, it has no other form or recognition, such as ISO-certification or accreditation, specific for health care institutions.

3. Visitation programme

The programme of visitation, as an external peer review, is focused on clinical practice, professional development, and quality of services (6). The standards are deduced implicitly from the clinical practice guidelines and from personal experiences. Visitation teams (supervision, round-ups) are clinicians mainly, most often from the same field. After the visitation by chosen colleagues, the assessment results in the form of a written report. The team reports are not publicized.

Visitation is a systematic form of external peer reviewing, popular in particular in the Netherlands (2). The whole model was inspired by visitations to clinics, which was operationalized as part of the quality assurance ever since 1967. The visitation programme has its roots in the health profession and it is carried out by medical professionals. The emphasis is placed on clinical performance, meaning the knowledge, skill, and attitude. In time, the visitation programme encompassed the organizational aspect as well.

Visitation is deemed closest to the actual clinical performance out of those four models, considering the structure, process, and outcome. Health professionals embrace this model most willingly, as well as accreditation, as they are the closest to their actual work performed and to peer review.

4. Accreditation

The model of accreditation was developed for the Joint Commission on Accreditation of Healthcare Organizations in the USA. Presently, it accredits almost 20.000 health institutions – hospitals, primary health care institutions, home care, long-term nursing institutions, laboratories, and network of group practice health care (16). Also, the first initiatives for accreditations started in the United States back in 1910 by Dr. Ernest Codman, after which the American Surgical College was founded in 1913, and the Programme for the Standardization of Hospitals started in 1917, as a prototype for accreditation (17). This programme was expected to secure recognition by professionals of those institutions which provide the best health care, as well as to stimulate those with poorer standards or equipment to strive for an improvement in the quality of performance. In 1951 the Joint Commission on Accreditation of Healthcare Organizations in the USA emerged out of this programme, the standards of which were initially set exclusively by health care professionals, who also made evaluation and used its results. As of 1965, when the state health care programme for the aged was established (Medicare), other stakeholders in the health care system became the users of accreditation results, too: first the government, then the health insurance companies, and finally the general population (16). Since 1997 the yearly reports on the performances of accredited hospitals can be found at the Joint Commission on Accreditation of Hospitals' Web site http://www.jcrinc.com (18). It is worth noting that more than 96% of hospital beds in the USA today are in accredited hospitals (16). From the USA the accreditation spread out to Canada, Australia, New Zealand, and in the last two decades of the twentieth century also to European countries. Its development is most evident in Great Britain, Spain, Portugal, the Netherlands, Finland, while in France and Italy it is on statutory basis.

The first European experiences with accreditation started much later than in the USA, though there were other external mechanisms for quality improvement in European countries which were predominantly based on medical audit and peer review (19).

Thus, the pilot programme of hospital accreditation which started in 1990 in Great Britain is a good example of developing the accreditation process. This programme was meant for small communal hospitals (57 altogether) with less than 50 beds (19,20). Out of those 57 hospitals, 43 were included voluntarily in the programme, and in two years 37 became accredited by the hospital accreditation programme. The main goal of the pilot programme was to instigate effectiveness (efficiency) of hospitals in a community, and to spread the ideas of good organizational practice. Local authorities

financed and appointed two members each for this pilot programme. An independent body for accreditation was also established. The body managed the programme and evaluated the reports on hospitals included by the programme. Initial standards used for accreditation were designed according to the 1988 publication by the national association of health authorities: »Towards the Practice Guidelines in Small Hospitals«. Those standards were derived from systematic observation of the organizational practice in small hospitals, and were confirmed and widely accepted by 17 national bodies, including 7 Royal Societies. The standards themselves referred to general organization, clinical services, medical specialities, and auxiliary services. They provided for the assessment of purpose and rationale of services, managerial arrangements, equipment and hospital capacities, operational policy, staff work and their education. During the first phase the hospitals assessed the quality themselves by filling out questionnaires based on published standards. Then a team of at least 2 researchers (clinical specialists, or professional managers and general practitioners) from the established accreditation body made a visit to each hospital for the first time for a day. Each researcher came from a similar but distant hospital, after he went through a three-day training – theoretical and practical – in the field of standards, research evaluation, and report composition. Reexamination by the accreditation body included evaluation of the written report by each member. The implementation phase entailed sending of the final report by the accreditation body to the manager of the hospital included by the programme. The managers were encouraged to discuss those reports over with their staff, but also with financiers. Inspections by external teams were performed four times a year, and staffs from all the hospitals were invited to a meeting in order to exchange experiences they had in implementing the quality improvement. Their experiences were related to a considerable time consumed in the preparational phase for the accreditation, as well as to a sense of pressure at the time when assessment is done by external teams. The very challenge of external assessment, however, proved to be a strong motive to reexamine (or disclose) the operational policy of the institution, the existing reports, and data, too. Many of the managers were surprised at the scope of data and information referring to their hospitals which they did not use in their everyday work. Explicit identification of the fields where improvement was necessary, such as correctness of data, administration of drugs, admission policy and patient's discharge procedure, were also stimulating for a systematic participation of physicians in the hospital management to its benefit.

The reasons not to accredit certain number of hospitals included by this pilot programme referred to a lower quality in the spheres of medical procedure safety, keeping of medical records, and medical organization. Visits by

external professionals in the course of two years confirmed that 69% of what was recommended was implemented in the daily work.

It is interesting to note that complete expenditures for this two-year pilot programme for 57 small hospitals amounted to £ 47.000, which includes two permanent employees, external assessment teams' training, meetings of the accreditation body, visits to hospitals, and other expenses.

Accreditation in Great Britain, as opposed to the one in the USA, was not led in the beginning by medical professionals and it did not connect or integrate the existing mechanisms with the accreditation procedure itself, but that is where emphasis lies today in particular. Still, following the experience they had in Great Britain, other countries developed similar projects as well. Today it is clear that the accreditation of health institutions has its future, and discussions are centered around its integration with other external assessment mechanisms, and whether the proceedings should be regulated at the national level or not (6,21).

Concept of accreditation – advantages and limitations

Accreditation as applied to organizations refers to a systematic assessment of health institutions in relation to explicit standards by experts outside the health institutions (20). During the accreditation the assessment is done by multidisciplinary teams of health professionals in relation to published standards. Although accreditation may be expensive, it is performed most often by non-profit independent organizations. It is a process in which a professional association or a non-governmental organization issues authorizations to institutions stating that they are accredited based on their ability to meet the preset criteria. It is also the process through which an authorized agency or an organization evaluates and recognizes programmes or institutions which satisfy the preset standards.

Accreditation as a process is to be distinguished from the process of evaluation of work in health institutions, which is an obligation done by the government or its agencies when issuing the work permits (22).

Good point in the accreditation as an external quality assessment model is that it reflects in detail specific features of health care offered by a health institution. It is noted to have roots in peer reviewing as a mechanism used by a medical team to evaluate the quality of total care offered by a health organization, while evaluation is performed by medical workers of the same educational level (23). Advantage of the accreditation is that it uses perform-

ance indicators, insisting upon evidence based medicine, clinical indicators, and benchmarking as a process of quality assurance in which an organization sets its goals and measures up their realization comparing itself to products, services, and practice in other organizations recognized as leaders in their fields (9). The hospitals which most often participate in the accreditation process and thus have the largest experience, also note the following benefits (6):

- development of multidisciplinary teams,
- reexamination of the institution's operational policy,
- data system improvement,
- growth of local and national prestige, and
- stronger connections between hospital managers and institution (networking).

Comparing the accreditation with the EFQM model, there is less energy invested in conceptualization and vizualization of the health institution's nature as the organizational one. When various accreditation guidelines are analysed, it is percieved that they had originally been aimed at wards/functions in health institutions, and that only recently they were directed to the structure – process – outcome approach, the system of quality, and total quality management (2).

Even though it is obvious that accreditation differs from other external quality improvement mechanisms, it is still evident that it is complementary to them. Besides, there is today a need for all external mechanisms to converge in order to provide the standardization and possibility of making comparisons (3). The following are cited as characteristics of an effective external quality assessment programme, including accreditation (6):

- The programme gives a clear frame of reference describing the quality elements,
- It publishes open standards in order to provide an objective foundation for assessment,
- It is focused onto patients and it reflects horizontal clinical pathways rather than vertical managerial units,
- It incorporates clinical processes and results, reflecting observations by patients, medical staffs, and public,
- It instigates self-assessment providing the time framework and tools for internal assessment and development,

- It trains personnel who then assess the quality, and it promotes reliable assessments and reports,
- It measures systematically – describes and evaluates objectively adherence to standards,
- It renders incentives – it gives stength to improve and responses to assessment's recommendations,
- It communicates with other programmes – it promotes consistency and reciprocity, it reduces duplicating and burdening of the health care service with inspection,
- It quantifies improvements in time so that it shows the programme's effectivness, and
- It secures public accessibility to standards, assessment processes and results – it is transparent and responsibe to public.

Accreditation procedure

Accreditation as a process is usually based upon the external peer review system, using written standards by which the quality of activities, the services or organizations in the health care system are assessed (6,24). Medical professionals have the key role in this process.

It is still debated today as how to approach the procedure of accreditation which can be (25):

1. institutional, or
2. oriented to clinical service.

The institutional approach is focused onto the whole institution and its operation, it is simpler for implementation, and the responsibility in undertaking the improvement action is clearer. However, this approach does not heed patients' experiences much. As opposed to it, the approach oriented onto the clinical service reflects experiences of individual patients, it is more encompassing, covering up all aspects of patient's care and treatment. But, it is not always easy to define the clinical service, therefore this approach requires more time and repetition in case it should comprise all services which contribute to the health institutions' operation. This approach is deemed more advantageous if the quality improvement is developed in the primary health care as well, though numerous pilot schemes.

After the services are defined, the next step in the process of accredi-

tation is to establish an independent accreditation body. In this respect, different countries have different procedures and those bodies are established upon initiative by independent health experts, physicians' associations, societies for quality in health care, and even by the health authorities (ministries). It is noted in literature that certain countries have no clear criteria in establishing the accreditation body (26). With growing interest in accreditation and more initiatives by the International Society for Quality in Health Care (ISQua), the procedure for establishing the accreditation bodies was simplified, and those bodies get expert help for their development and in developing the national standards and services. As part of the ISQua, the ALPHA programme was developed to supply published international standards for the accreditation bodies in health care (ALPHA: Agenda for Leadership in Programs for Healthcare Accreditation) (21). There are 10 such standards and they can serve as guidelines in establishing the national accreditation bodies. The contents of these standards, which also incorporate the ISO requirements for similar bodies, is as follows (24):

1. *Standard:* Managership of the national accreditation body with the mission, values and vision, the strategic and operational planning, keeping the external communication with users, with professional, political, and financial bodies, and with other participants interested in improving the health care.
2. *Standard:* Organization and management of preformance which assures improvement of work and the quality improvement system, defines the accreditation body's statute, contracts, relations with accreditation users, and marketing.
3. *Standard:* Management of human resources, which includes planning, finding, selecting and appointing the persons to work in the accreditation body, their professional development and interpersonal relations.
4. *Standard:* Selection, education, and development, as well as employment of researches who are to participate in the external quality assessment, providing for their satisfaction with their work.
5. *Standard:* Management of finances and resources through systems which insure that strategies and goals will be attained with minimal risk.
6. *Standard:* Management of information which presumes gathering, keeping, and using the relevant and timely information needed by the accreditation body.
7. *Standard:* Management of quality assessment including the preparation of participants in the quality assessment procedure, satisfaction of their needs

after the assessment is done, stimulating the objective and consistent decision-making, implementation of improvement, and evaluation.

8. *Standard:* Accreditation process which implies maintaining of the accreditation system by defining clerly its purpose, responsibility in accreditation, and preserving its achievements, as well as keeping the documentation.
9. *Standard:* Development of accreditation standards which satisfy international principles to be developed, implemented, evaluated, and modernized in a planned way, together with development of clinical practice guidelines.
10. *Standard:* Educational services which are systematically designed and implemented so that they satisfy the quality standards and needs of the accreditation users.

The key elements in the accreditation procedure, after defining the service to be accredited, and after the national accreditation body was established, are as follows (25):

1. Setting up the standards;
2. Assessment of performance in relation to set standards; and
3. Consent to the assessment, and implementation of the action which is to correct shortcomings identified during assessment.

Setting up the standards is an integral part of continuous quality improvement in a country, with discussions still going on about the balance between the national and local standards, the level at which the standards will be set up, and as to who is to set those standards up, with a clear recommendation for them to be published (27,28). The basic characteristics of the standards in accreditation system are required to be (19,25):

- explicite,
- objective,
- measurable,
- based upon evidence, if such exist,
- connected to the structure (adequacy and organization of resources – personnel, buildings, equipment, amd financial means), the process (clinical practice and interventions), and to the outcome (intervention results), and
- regularly revised in light of the latest evidence and experiences.

Upon initiative of the International Society for Quality in Health Care (ISQua), as in the case of recommendations for establishing the national accreditation body, the ALPHA programme institutionalized international principles for formulating the national standards which are to be respected in the national accreditation procedure (21). There are six of those international principles and they refer to:

1. ways of presenting their contents,
2. clarity of definition,
3. clarity of scope,
4. comprehensive and clear structure,
5. formulation by well defined process, and
6. receptiveness to performance measurement.

Performance assessment in the accreditation procedure has its external elements and involves peer review. It is advisable that peer review be multidisciplinary and that it reviews contributions by all disciplines in offering the health care quality. The assessment itself is supposed to be based upon objective and written evidence, and on visits to the institution to be accredited. It should be cyclic – the external assessment is to be performed in certain intervals (differing from country to country: once a year, once in 3-4 years, etc.). Also, the assessment visits are to be more often in case certain problems have been noted, and if the improvement action has been defined. It is an important fact that all accreditation systems have explicit organizational standards in reference to which the institution itself is assessed prior to the structured visit by professionals out of the institution, who then submit a written report with acclaims and recommendations for development both to the independent accreditation body and to the institution itself (6). Accreditation can be conferred for certain period of time, or it can be withdrawn by the independent assessment body in case the hospital does not comply with the defined assessment programme.

The body responsible for the accreditation process, assessing the compliance with defined standards, has the right to make public its findings, and to plan repeated visits to the institution for the purpose of external peer reviewing. However, the implementation action is under full responsibility of all employees in a given institution.

Taking into account the existing accreditation programmes in many countries, further development of this system is deemed necessary so as to (4,6,19):

- provide better co-ordination with existing external quality assessment programmes at national and international levels,
- develop and institutionalize the standards which are to be relevant to patients,
- emphasize the quality connected to the clinical performance, reviewing concomitantly all aspects of health care offered to patients, and
- avoid separate »right« solutions for all aspects of health care quality, but to develop a general framework for constant improvement of quality in healthcare.

For the accreditation procedure to start in any country, however, it is necessary to create the national strategic framework for continuous quality improvement in healthcare, where the accreditation itself is but one of its segments (4). Even though the work of the accreditation body (commission, board, association) is independent, it must be acknowledged either by the government or the health institutions, or by a professional association (21,29). The strategic framework is to specify whether the accreditation procedure is to be legally regulated or voluntary, with the voluntary principle referring to the participation by health institutions in this procedure remaining quite important – the health institutions recognize their interests themselves. Experience also shows that development of the accreditation procedure requires 2 to 3 years, and pilot projects are first recommended with one or several health institutions participating in those projects (6).

International projects and experiences with accreditation in European countries

Considerable interest in the accreditation procedure is confirmed by international projects which were/are aimed at analysing its basic characteristics, advantages, and limitations in various countries. So far, the most prominent projects in the European countries are theExPeRT Project and the ALPHA programme (14,21,26,30).

ExPeRT project (*External peer review programs*) has been financed since 1996 by the European Union, aimed at analysing and exchanging experiences related to external peer reviewing and organizational standards for the health service assessment, particularly the accreditation process, along with recognition of achievements and creation of network among countries for the exchange of experiences (networking). The goals of this project are also to

gather and disseminate various concepts and experience in implementation and training, as well as to support the integration with internal quality assessment mechanisms. Countris of the European Union were encompassed by this project. The ISO standards model, EFQM model, visitation, and accreditation were identified as basic external mechanisms in this project.

ALPHA programme (*Agenda for Leadership in Programs for Healthcare Accreditation*) was initiated by the International Society for Quality in Healthcare (ISQua) in Italy in 1994, as a discussion forum, and as a way of learning about accreditation based upon experience of others, and the programme is active since 1999. In a sense, this programme gained ground as a response to numerous pressures to introduce ISO standards for the quality assessment in health care, aimed at protecting and improving those external mechanisms originating in the health care system itself, most notably the accreditation. So far, the ALPHA programme is part of an important recommendation to adopt principles for the set standards for all national accreditation systems, respecting the specifics of individual countries. An ALPHA programme study gives recommendations for accreditation bodies which are to accredit health insitutions in a given country, as well as recommendations for the accreditation programmes themselves. Today ALPHA leads, evaluates, and accredits the national health care accreditation bodies, helping them to achieve international »excellence«. This programme is also capable of aiding the assessment and improvement of standards of national organizations, in relation to internationally approved standard principles in health care, and to assist in developing accreditation programmes in a given country. In this way the national accreditation organization is to show not only that its system and process of operating satisfies the ALPHA international standards, but also that national standards are in concordance with ALPHA international standard principles for health care. ALPHA standards and principles are found at the Web site http://www.isqua.org.au. Members of the ALPHA Council – Accreditation Federation are representatives from 13 countries with greatest experience in accreditation procedure, as well as representatives from the World Health Organization, the World Bank, and the International Hospital Federation. ALPHA provides programme packages for the development of accreditation, and also the relevant articles published in this field.

EXERCISES: Accreditation of Health Institutions as an External Tool for Quality Improvement

Task 1. After introductory lecture students will participate in nominal group technique in order to recognize and to rank the field in the quality of health care where organizational, managerial, or other improvements are necessary, such as waiting lists, admission policy, medical records keeping, patient's discharge procedure, administration of drugs, working in multidisciplinary teams, patient satisfaction, etc. The necessary time for this exercise is 45 minutes, if the group is consisted from 20 students.

Students will be divided in two groups according to their preferences (hospitals or primary health care institution). Each student will give an example of bad quality in the health care institutions, according to his – her experience and should be warned to be ready to explain it later. Teacher will write down each example on the flip chart. After listing the examples students will select 5 conditions of bad quality and then rank them according to importance, by using marks from 1 to 5 (where 5 is the most important). All individual marks will be summed up and three conditions of bad quality will be selected in such way for further discussion. Students who proposed the selected condition are going to explain what the reasons for their selection were.

Task 2. The work will continue in small groups (4 to 5 students), divided according to country or working place, to discuss the possibilities for solutions and improvement in their own environment. For this exercise additional 1,5 hour are requested. After small group discussion presentations will be in front of the whole group. Teacher will summarize the reports pointing out the standards necessary to be reached in order to be ready for the accreditation procedure. It is recommended to follow existing standards of good quality in health care institutions.

Task 3. The third exercise will be to discuss, within the country (or working place) small groups, the necessary procedure for development of national accreditation system. Teacher will advise students to follow existing models and experience and to highlight their advantages and obstacles in the case of application within the country of SEE region. This exercise required 3 hours under the supervision because students are obliged to search Internet resources of International Society for Quality in Health Care (http://www.isqua.org.au) as well as Joint Commission on Accreditation of Hospitals (http://www.jcaho.org/).

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Project Management**
Module: 2.11	**ECTS (suggested): 1.0**
Authors, degrees, institutions	Silvia-Gabriela Scîntee Part-time lecturer at the University of Medicine and Pharmacy „Carol Davila" Bucharest, Department of Public Health and Management Public Health Consultant at the Institute of Public Health Bucharest Adriana Galan, IT Specialist Part-time senior lecturer at the University of Medicine and Pharmacy, Department of Public Health and Management, at post-graduate level
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Keywords	Project management, project proposal writing, project development, project implementation
Learning objectives	At the end of this course, students should be able to: • identify what it is needed to know and do to set up a project; • identify the needs and to set up the priorities; • prepare a Preliminary Brief; • plan and schedule a project; • set up a monitoring and evaluation plan; • develop a project proposal.
Abstract	This course concerns Basic concepts of Project Management, Initiation Phase, Preliminary brief, Detailed Planning, Scheduling, Implementation and Completion. At the end of this course, a project draft is proposed to be designed by the students.
Teaching methods	Lectures, interactive presentation of key concepts (overheads or PowerPoint presentation), group discussions, groups' assignments. Work in small groups (4-5 persons) and an overhead will be presented by each group after each assignment.
Specific recommendations for teacher	It is recommended that this module is organized within 1.0 ECTS credit. The work under supervision is consisting from lecture (5 hours), supervised assignment solving (5 hours), while individual work is related to collect data and to prepare the project proposal draft (20 hours).
Assessment of Students	Final draft of a project proposal.

PROJECT MANAGEMENT

Silvia-Gabriela Scîntee, Adriana Galan

Project is not a new concept. Projects have been carried on since the inception of the organized human existence and less complex projects are very common in our daily life. Any work which has a beginning and an end, is planned and controlled and creates change can be called „project" (1).

Very often „the project" is considered synonymous with „the programme". Still, there is a difference between the two terms. A programme is more exhaustive than a project and has larger time limits. A programme can have more projects as component parts.

Projects are classified under four main headings (2):

1. Industrial projects (civil engineering, construction, petrochemical, mining and quarrying projects): Usually large projects, requiring massive capital investment and rigorous management, that incur special risks as the implementation phase is conducted remote from project manager's office.

2. Manufacturing projects (production of equipment or machinery): These are conducted in a factory, but sometimes requiring work away from the company for installation, customer training, subsequent service and maintenance.

3. Management projects: Arise in each organization as a part of its work or when a change is envisaged. Examples: restructuring the organization, relocating the headquarter, refurbishing an office, planning a training session or conference, introducing new service, introducing a new computer system.

4. Research projects: Unlike other types of projects their final objectives are difficult or impossible to define.

Characteristics of the project

Regardless their type, the project has five common characteristics (3): it creates change, it has various goals and objectives, it is unique, it is limited in time and scope, and it involves a variety of resources

1. A project creates change. When a project is conducted the routines and regular work within an organization is disrupted by unfamiliar, new activities. This could lead to resistance from the staff as people do not like to

have their existing work altered. More than that, those working in the project have to report to the supervisor of the routine work and also to the supervisor for the project work. Other sources for resistance could be: conflict of interests, low tolerance to change, different perception of the need to change, misunderstanding and lack of trust.

The Project Manager could use various methods of change management to face this resistance in accordance with how much time, money and power he has. Examples of such methods are:

- education and communication – the best method which unfortunately takes a lot of time and money
- involvement of people in project development – also good but still takes time
- supporting people to facilitate change – takes also time
- negotiating with people – takes less time, but a compromise has to be reached
- manipulating people – quick and cheap method, but can fail if people feel like being used
- coercion – the quickest and the cheapest, but in the same time has the highest probability to fail

2. A project has various goals and objectives. There are three types of goals and objectives for any project (3):

- performance and quality – the end result of the project must be fit for the purpose of which it was intended
- budget – the money spent on the project must correspond to the authorised expenditure
- time of completion – all stages of the project should take place at their specified dates and total completion date should correspond to the planned finish date

The Project Manager should find a balance between these three attributes: time, quality and cost. If the project finishes before the planned completion date, money may be lost. If the project is extended beyond its scheduled finish date is likely to have increased costs. In both cases the quality might suffer.

3. A project is unique. There are not two identical projects. Despite the existence of a standard methodology for project development and of a same basic procedure no matter the complexity of the project, the work content of every project varies.

The Project Manager needs to develop a plan taking into account the particular circumstances that is both strong and flexible enough to accommodate changes in those circumstances.

4. A project is limited in time and scope. These are the main characteristics that make the difference between the project and the programme. A programme is not necessarily limited in time and its scope is more comprehensive. A project is limited in time and scope, having a beginning and an end very well defined.

A great deal of the Project Manager's effort is focused on the completion of the project at the scheduled finish date. There are a lot of tools that can be used in time planning, from timetables – the simplest, which represent a list of activities with their starting and finishing dates, to Gantt Chart and Critical Path - more complex methods that take into account the dependency degree between activities.

5. A project involves a variety of resources. When a project resource planning is discussed, most people will think of resources first in terms of money. But resources are also: people, equipment, materials and time. It is very difficult to forecast the precise quantity of resources and the moment when these will be used. Still, the necessary resources should be estimated and scheduled. It is also necessary to specify how these resources will be obtained.

As there are a lot of factors that could impede the utilization of resources according to the schedule, the Project Manager must periodically evaluate the progress and if necessary re-schedule resources.

The phases of project management

The above characteristics of the project have implications for the project management that is defined as „the process by which the project manager plans and controls the tasks within the projects and the resources on which the organisation draws to carry out the projects." (1)

All projects may be planned and carried out in the following four phases, known also as „the project's life cycle": initiation, planning, implementation and completion.

Initiation. Projects arise because of a need. So, in the initiation phase there are determined: the need for the project development, the terms of reference (what has to be done, what would be the expected results), the feasibility of the project and also it is created a workable environment for the project. This is considered the most important phase in the whole project (1), even if is the shortest one usually taking no more than 5% of the project lifetime.

Planning. In the planning phase, which usually takes 20% of the project duration, the tasks, resources, effects and needs of the project are examined in depth (1). Planning is under the responsibility of the Project Manager, either done by himself in isolation or by a planning team. During this phase it is decided what should be done, by whom, at what point in time and with what resources in order to reach the project's objectives. It is important in the planning process to forecast the potential constraints that might affect the implementation phase and to design strategies for overcoming them.

Implementation. Implementation is the longest phase of a project (60% of the project duration) in which the project plan is put into operation. The implementation process is monitored and controlled in order to ensure the obtaining of quality results on time and within budget. Monitoring is a continuous oversight of the project execution that assists in its supervision and assures that it proceeds according to plan. On the basis of controlling the project progress is checked against the plan and corrective action is taken where necessary.

Completion. In the last phase the whole project is reviewed, the final report is presented and the resources are re-allocated. This phase usually takes 15% of the project duration.

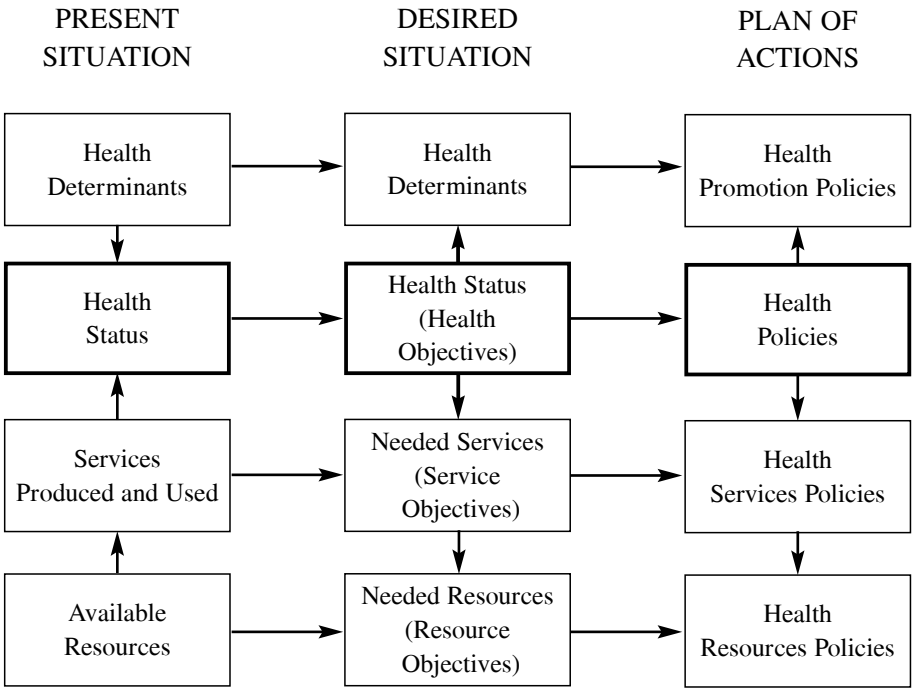
1. Initiation (pre-planning) phase

This is generally considered the most important phase in any project. During this phase, **what should be done** under the project is determined (1). This phase includes usually the following steps:

1. Situational analysis
2. Health problems identification
3. Priority setting
4. Establish goal and objectives
5. Feasibility study

1.1. Situational Analysis

Situational Analysis represents the first step of the pre-planning phase for any project. It represents an assessment of the health status of the population (can be a „target" population) and of the health care system in relation with the internal and external environment. According to R. Pineault (4), the general framework of analysis can be conceptualised as follows:



The main goal of this step is to define and establish valid criteria for the identification of priority health problems. Another important goal is to provide data and information necessary to design objectives and strategic choices. It also represents a support for the feasibility evaluation.

Data and information collected during this step cover the following domains:

- Assess the internal and external environment (review of economic, social and health objectives and policies)
- Health status and related determinants assessment (mortality and morbidity rates, disability, life expectancy, lifestyle indicators, trends etc.)
- Health system assessment (public/private institutions, accessibility for health care, population coverage with services, patient flow within the health care system, etc.)

- Resources – human, material and financial

The main output of this step is represented by a comprehensive document offering a picture of the existing situation.

1.2. Health problems identification

The main goal of this step, involving more or less a subjective judgement, is to obtain a list of health problems. According to R.Pineault (4), a **health problem** represents a deficient health status as perceived by individuals, physicians or communities.

There are several methods described in the literature for problem identification. R.Pineault (4) has described three categories of approaches:

- Based on existing health system indicators
- Based on special surveys
- Based on consensus research

For each approach, he described the methods used in order to identify the health problems. The following table presents the methods used within each approach:

Approach	Methods	Needed Information
Based on existing health system indicators	Socio-demographic (associated to the health status and service utilisation)	Population structure, age pyramid, natality rate, crude mortality rate, fertility rate, average income level, level/rate of poverty, rate of unemployment, level of education
	Health (mortality, morbidity, risk factors and disability)	Crude and specific mortality rates, infant mortality rate, life expectancy at birth and certain ages, standardised mortality rates/ratio Incidence/prevalence rates, hospitalised morbidity, frequency of different risk factors, attributable deaths for certain risk factors, potential years of life lost due to certain risk factors DALY, QALY
	Health services utilisation	Medical visits rate, surgical interventions rate, number of diagnosis tests (e.g. laboratory, x-rays etc.), number of referrals, hospitalisation rate (number of discharges), average length of stay
	Health resources	Number and types of health care units, population coverage with different types of health care professionals (physicians, nurses, dentists etc.), health care expenditures

Based on special surveys	Sampling	Health Interview Surveys (perceived health status) Health Examination Surveys (based on clinical exams)
Based on consensus research	Delphi Technique	Evaluate the opinion of certain experts on prevalent problems in a community. It is based on a group process of judgement, even if the experts don't communicate directly. The experts answer to successive posted questionnaires until sufficient level of consensus is reached.
	Nominal Group Technique	Medical visits rate, surgical interventions rate, number of diagnosis tests (e.g. laboratory, x-rays etc.), number of referrals, hospitalisation rate (number of discharges), average length of stay
	Brain writing Technique	The difference from the Nominal Group Technique is that all the ideas concerning the problems are presented (written on a table) from the very beginning to all participants. It is possible to reach the consensus also by voting or by final discussion.
	Brainstorming Technique	It is mainly useful to generate ideas (mostly recommended for problem analysis and judgement of choices). Experts are invited and encouraged to come up with original ideas.
	Community Forum	Public is invited to express community problems.

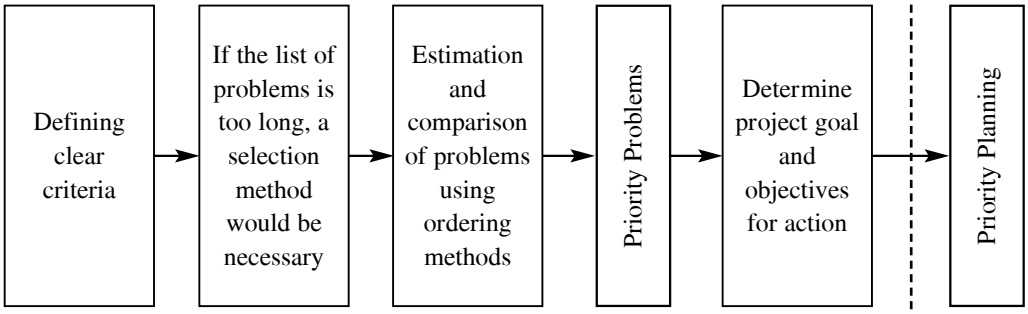
In order to judge the identification of one problem, several criteria can be used:

- Problem's dimension (usually its frequency within a population)
- Problem's severity (usually measured by premature deaths, potential years of life lost, disability)
- Trends

1.3. Priority setting

Priority setting means to select those problems identified during the previous step that can be the object of an intervention. It is actually a process of comparisons and decision-making, based on special methods and techniques for ordering the identified problems according to their importance.

The conceptual framework of priority setting process was also described by R. Pineault (4):



Three main criteria are used in order to prioritise the identified problems:

- *problem's dimension* (incidence / prevalence, premature deaths, avoidable deaths, invalidity, the size of the population at risk, the impact on medical services, family, society, etc.)
- *intervention capacity* (knowledge on the disease / associated risk factors, prevention possibilities)
- *existing resources for intervention* (existing services, qualified personnel, population accessibility to health services)

There is a wide range of priority setting tools (ranking methods) that can start from a simple grid analysis, and ends with complex methods. Based on a large number of criteria, these tools allow the problems ranking.

If the list of identified problems is too long (>40), it would be necessary to shorten this list, using the Selection Method.

1.3.1 Selection Method

Its main purpose consists in rejecting the less important problems from the list. The result of selection method is a shorter list of more important problems, and not necessarily a problem ranking.

A selection criteria is established from the beginning. A group of 3-5 experts will select the most important and less important problems during several meetings:

- *first meeting*: the most important and least important problems are selected from the initial list, and put on separate lists (important and less important problems);

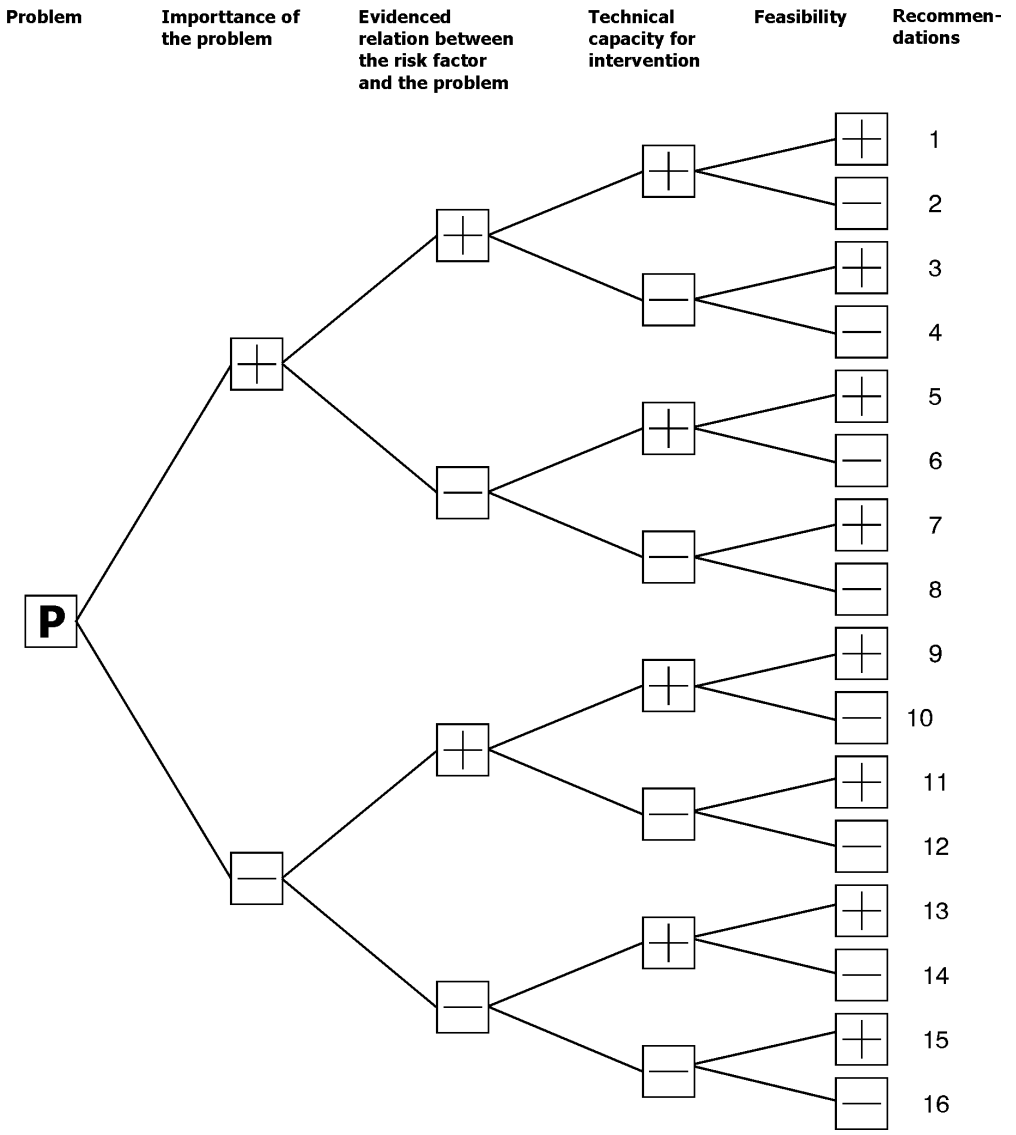
- *second meeting*: from the remaining list, the first 2 most important problems and the last 2 less important problems are again selected and put on the 2 previous lists;
- *third meeting*: from the remaining list after the second meeting, the first 4 most important problems and last 4 less important are again selected and put on the 2 lists; and
- the process stops when the list of most important problems contains no more than 10 problems.

R. Pineault has grouped the priority setting (ranking) tools into two categories (4):

1. specific methods for health planning. Within this category, two methods are mostly used:
   - *Grid Analysis*
   - *Hanlon Method*
2. general ranking methods. Within this category, several methods can be mentioned:
   - *Anchored rating scale*
   - *Paired comparison*
   - *Pooled rank*

Grid Analysis

It allows formulating recommendations on priorities. It takes into account the problem importance, its evidenced relationship with associated risk factors, technical potential for problem solving, and intervention feasibility. The method allows establishing 16 possibilities of recommendations in descending order of priority for each problem. A general Grid Analysis is presented on the next page:



The results can be summarised in a final table as follows:

	Problem importance	Evidenced relationship with associated risk factors	Technical potential for problem solving	Intervention feasibility	Recommendation from the Grid Analysis
Problem 1	+	+	+	-	2
Problem 2	-	+	+	+	9
Problem n	-	+	+	-	10

According to this method, Problem 1 is considered the highest priority.

Hanlon Method

It ranks the priorities taking into account 4 components: problem magnitude (A), problem severity (B), solution effectiveness (C) and intervention feasibility (D).

A. Problem magnitude is usually measured by rates or index (a score is assigned for each problem; score values ranges between 1 and 10. Value 10 represents the highest frequency in a population).

B. Problem severity is usually measured by mortality rates, potential years of life lost, DALY, associated costs (a score is assigned for each criteria; score values ranges between 1 and 10. A final score is calculated for each problem, as the average of previous scores. Value 10 represents the most severe situation).

C. Solution effectiveness must measure the availability of resources and technologies able to improve the problem. A score is also assigned for each problem, ranging between 0.5 and 1.5. Value 0.5 indicates that the problem is difficult to be solved, while 1.5 indicates that there are possibilities to solve the problem. It is mostly a subjective judgement.

D. Intervention feasibility is also a subjective judgement taking into account the following components for each problem: pertinence (P), economic feasibility (E), acceptability (A), resources availability (R) and legal framework (L). A score is assigned for each component, 1 means a positive answer, 0 means a negative answer.

A final composite index is computed for each problem based on the following formula:

$$P_{1\ldots\ldots n} = [(A+B) \times C \times D]$$

The highest score corresponds to the most priority problem.

Anchored rating scale

A linear scale is used, ranging between 0 and 1 (1=extremely important problem; 0.75=very important; 0.5=important; 0.25=less important; 0=problem can be neglected). Each expert is asked to place every problem on this scale. Finally, a mean is calculated for each problem, having in the end a hierarchy.

Paired comparison

Problems are compared two by two. During each step, a problem is compared with all the others; for each comparison the most important problem is marked. For each problem it is computed in the end of sum of favourable situations.

For example, if there are 5 problems (A, B, C, D, E) to be ranked, the method can be summarised into the following table:

Problem	**Paired comparison (selected problem is marked)**				**Obtained score or percent**
A	A B√	A C√	A√ D	A E√	A=1 or 10%
B		B√ C	B√ D	B E√	B=3 or 30%
C			C√ D	C E√	C=2 or 20%
D				D E√	D=0 or 0%
E					E=4 or 40%

Pooled rank

A group of experts is ranking the problems, starting with the most important one (highest rank) and ending with the least important (lowest rank). Each problem receives a rank from each expert. A mean rank is finally computed for each problem.

1.4. Establish goal and objectives

In establishing the goal and the objectives, the following elements should be taken into account:

- the goal and the objectives of the national health policy
- the goal and the objectives of the national health programme adressing the identified problem (if there is one)

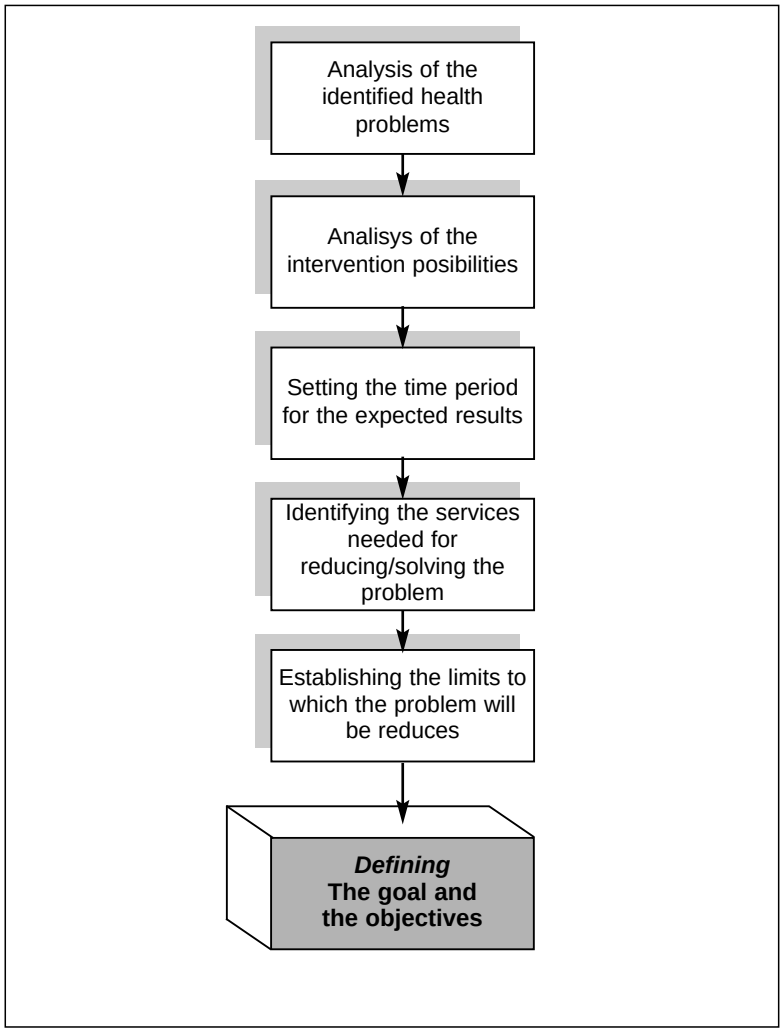
- local health policies
- international health standards and objectives

There is also necessary to define:

- the target population
- the geographical area
- the extent to which the problem can be reduced or solved
- the time during which the problem should be reduced or solved

Stages towards defining the goal and objectives are presented in the Figure 1.

Figure 1. Stages towards defining the goal and objectives



A ***goal*** is a long term result toward a project is aiming. In health, a goal usually refers to the solving or reduction of a health problem. There is not necessary to specify any quantitative outcome or time limits (5).

Ex. „To increase the reproductive health by reducing the number of abortions and undesired pregnancies in students from Bucharest University"

An ***objective*** is a desired outcome to be reached in a certain period of time. An objective measures the progress towards the stated goal. For this it is necessary to be quantified and to establish time limits. In defining an objective the following have to be specified:

- *what* will be achieved
- *how much* (to what extent)
- *when* is expected the result
- *who* will benefit
- *where* is expected the result

In defining objectives could also be used the acronym SMART (S = specific, M = measurable, A = agreed upon, R = realistic, T = timebound). It is recommended a limited number of objectives (3 – 5). In accordance to the project complexity there can be established different types of objectives:

- *General objective* – which would be the result expected at the completion of the project and shows how much the situation will improve;

  Ex. „To reduce by 50% the number of abortions and undesired pregnancies in students from Bucharest University, between 2000-2002"

- *Intermediary objective* – measures the progress towards the achievement of the general objective expected at a certain point in time;

  Ex. „To reduce by 25% the number of abortions and undesired pregnancies in students from Bucharest University, until December 31, 2001"

- *Specific objectives* – represent specific results that would assure the achievement of the intermediary and general objectives;

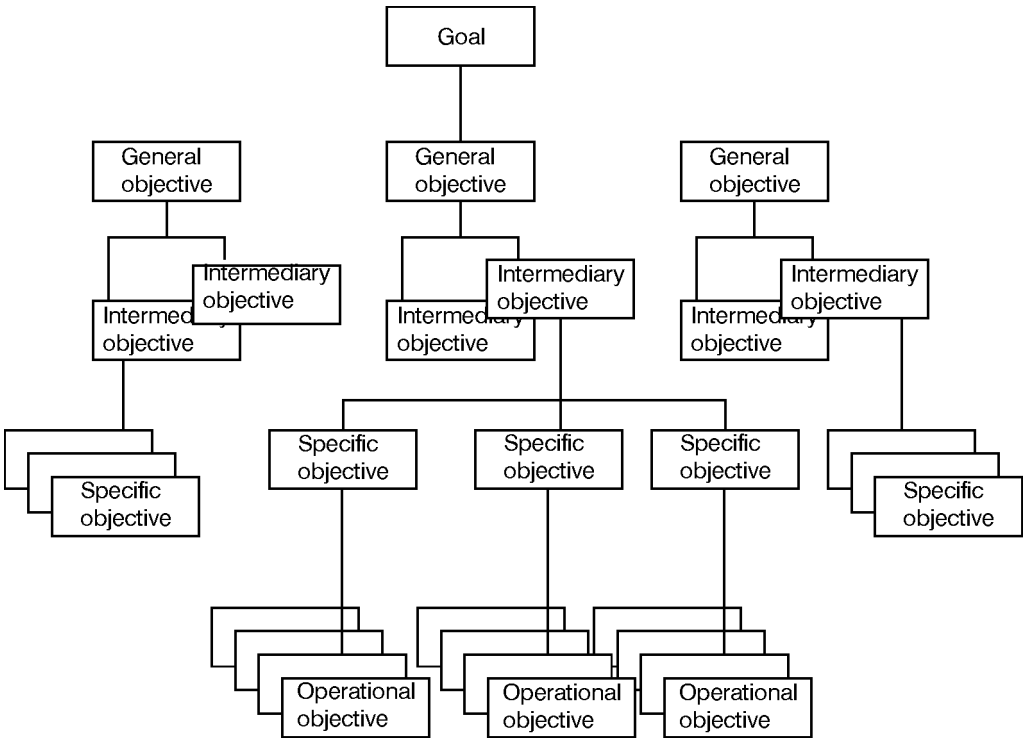
  Ex. „To increase the information level of the students from Bucharest University in regards with contraceptive methods"

- *Operational objectives* – that are in fact, the actions to be taken in order to reach the objectives;

  Ex. „To freely distribute 10000 brochures on contraceptive methods to the students from Bucharest University, between January – June 2000"

There are sequence and interdependence between different types of objectives (Figure 2).

Figure 2. Sequence and interdependence between different types of objectives



1.5. Feasibility Study

The aim of this step consists in the evaluation of alternative proposed strategies in order to select the best one to be further implemented.

The evaluation is focusing on three main aspects (6):

- political feasibility
- technical feasibility
- institutional feasibility
- financial feasibility

Political feasibility is focusing on the favourable / unfavourable political environment, on the agreement / disagreement of all key stakeholders involved.

Technical feasibility usually takes into account three aspects:

- provision of requested services needed to achieve the proposed activities (existence and availability of necessary technology)
- the proposed offer of services (Meet the population needs? Are the services accessible? Does it attain the target population?)
- impact on health status (Do the proposed services improve the health status? Do the services contribute to the achievement of project objectives?)

Institutional feasibility is focusing on:

- estimation of the necessary types of institutions and their geographical distribution, for the achievement of objectives (Do they exist? Do they need restructuring / rethinking? New institutions are needed to be created?)
- staff (Existing staff has sufficient skills? Are training sessions necessary? New staff is necessary to be hired?)
- administrative and managerial capacity (New capacities are needed? Is the logistic support available?)

Financial feasibility takes into account:

- estimation of total costs of necessary resources
- estimation of running costs of the project
- identification of possible financial sources

1.6. Preliminary brief

A brief contains the key information about the project, having a multiple use:

- to proceed a feasibility analysis
- to ask for funds
- to direct the further planning of the project

A preliminary brief should include:

- *Project name*
- *Background (presenting the identified problem and the chosen solution)*
- *Goal and objectives*

- *The expected results*
- *The required budget and time*
- *Methods of monitoring and evaluation*
- *Information about the organization*

2. Detailed planning and scheduling

After objectives setting, a detailed plan of action is developed for each of them. Action plans specify what should be done, by whom, where and when, being the bridge between stated objectives and the practical work. Action plans could be seen as means and methods by which the objectives will be reached. A project plan should be detailed enough in order to:

- provide a clear image on the activities
- clarify for the project team the sequence and interdependence of activities
- facilitate the correct estimation of the necessary resources

There are described eight steps to be taken for the detailed planning of a project (1):

1. identifying the tasks (deciding what has to be done)
2. classifying the tasks and placing them in a logical order (some tasks are concerned with running the project, others are concerned with the actual work content of the project)
3. studying the implications (how the project could affect the organization policy, what is the impact on the clients, the public, the environment, what is the relationship with other projects)
4. estimating resource requirements
5. identifying the project hierarchy
6. clarifying the levels of authority (and setting clear areas of responsibilities for each person)
7. setting up the procedures needed to monitor and control the project
8. setting ground rules (informing the team of what is expected as a group norm)

In order to schedule the work content and resources of a project there

are a lot of tools that a manager could use. The most known are *Gantt Chart*, and the *Critical Path Method*.

The *Gantt Chart* is recommended for the uncomplicated projects. A Gantt Chart is a simple display of tasks (listed in the first column) together with their duration of accomplishment (presented as horizontal bars alongside each task). The time periods could be presented either in days, weeks, months, quarters or years (Figure 3).

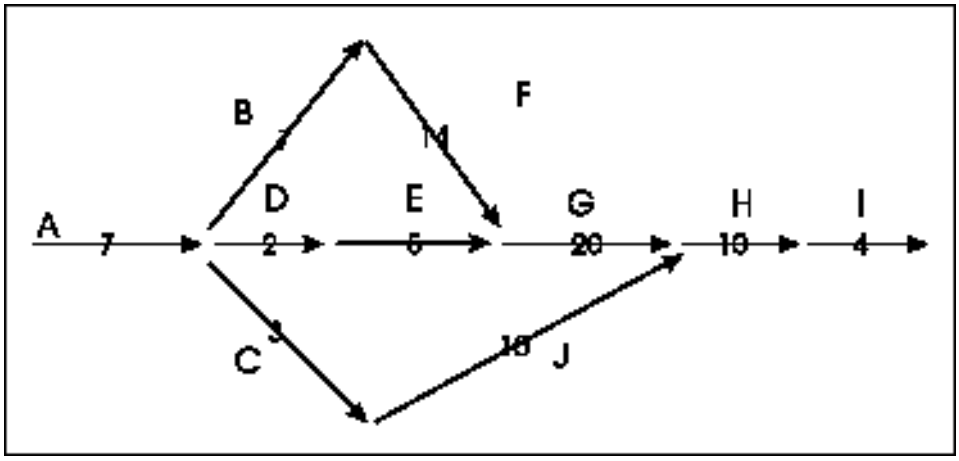
For more complex projects in which the dependencies between activities need to be shown a *PERT diagram* could be used. PERT (Program Evaluation and Review Technique) is a network tool relating tasks to each other on the basis of time and precedence and producing a critical path through the project (7).

Each activity is represented by an arrow, on which the activity is described together with the estimated duration. *Critical path* is the longest path through the network of tasks that defines the duration of the project (7). For this path the Project manager has to worry about as any delay of an activity could lead to the delay of the project end (Figure 4).

Figure 3. Sample of a Gantt Chart

Tasks	April	May	June	July	August	September
Methodology Development						
Testing the questionnaire validity						
Informing District Health Authorities and training of operators						
Data collection						
Data analysis						
Development of the final report and dissemination of the results						

Figure 4. Example of a critical path



A = Methodology development; D = Informing authorities; E = Accept of authorities; G = Data collection; H = Data analysis; I = Final report; B = Testing questionnaire; F = Pilot survey; C = Training operators; J = Developing software and online data collection

A-B-F-G-H-I = 7+7+14+20+10+4 = 62 days

A-D-E-G-H-I = 7+2+5+20+10+4 = 48 days

A-C-J-H-I = 7+3+10+10+4 = 34 days

In this example the first path has to be taken as critical path.

The financial resources should also be planned. This is done by using the budget. Budget estimation is very important for a project because:

- is one of the essential elements a funding agency is looking for
- represent a basis for the financial control that will compare the plan with its execution
- helps in choosing the most cost-effective projects, attaining the allocate efficiency
- allows a better resource allocation within a project, attaining the operational efficiency

In order to estimate the budget it is necessary to:

- list all types of required resources for each activity
- determinate the quantity of each type of resources
- estimate the unitary cost for each type of resources
- calculate the total cost of each type of resources

- discount future costs if the project duration is more than one year

The costs of each activity are usually presented in four expenditure categories:

- personnel (like salaries, training, per diem, etc.)
- equipment and materials (including also maintenance costs)
- facilities (ex. renting, modifying or building a new office)
- support expenditures

A special category is represented by incidentals which usually should not exceed 10% of the total cost of the project should be justified.

The budget should also contain the sources of funding. These could be represented by the organization's own funds or there could be multiple financing organizations. Each source will be specified for in separate columns.

The estimated costs could be presented like in the following table:

Expenditure Categories	Activity description	Cost per activity	Own funds	Requested funds
1. Personnel - salaries - accomodation - perdiem - transport	***EXAMPLE:*** - project coordinator salary 100$/month x 12 months - 15 participants in a training course held in Bucharest x 5 days x 30$per diem - 2 trainers x 5 days x 50$ fee/day	 1200$ 2250$ 500$		 1200$ 2250$ 500$
SUBTOTAL		**3950$**		**3950$**
2. Equipments and materials	- multiplying course materials 5$/participant/day x 5 days x 15 participants	375$		375$
SUBTOTAL		**375$**		**375$**
3. Facilities	- classroom rent 100$/day x 5 days	500$	500$	
SUBTOTAL		**500$**	**500$**	
4. Support expenditures	- communications	300$	300$	
SUBTOTAL		**300$**	**300$**	
5. Incidentals (reimbursed on the basis of receipts)				
TOTAL GENERAL		**5125$**	**800$**	**4325$**

A funding agency might have its own administrative procedures, so before submitting a project the agency should be contacted and should be asked about the necessary documents and the recommended budget format.

The plan is many times negotiated with the funding organization. Usually the project should be in accordance with donors' policies and priorities. When deciding to fund a project a financing organization is mainly interested in:

- project justification
- technical capacity for running the project
- compatibility with other projects
- measurable and acceptable benefits
- detailed and justified costs
- sustainability (how the impact of the project will be continued after the project funding has ceased)
- a clear monitoring plan
- previous experience of the applicant
- collaboration with other partners
- multiple financing sources

3. Implementation

The implementation phase consists in putting the project plan into operation once all approvements and authorizations have been received. The plan should be flexible as even after being approved, in the implementation phase, changes might inevitably occur because of the *internal* or *external factors*.

Examples of *internal factors* could be: a key person that leaves the team, poor communication on somebody's part, delays in equipment procurement or in funds release.

External factors are less under the Project Manager's control. Examples of *external factors* are: partners who leave the project, change in donor's policy, change in health policy or legislation, change in organization's structure.

Implementation is initiated by the Project Manager and the other authorities responsible for the project by developing the job description for the

Project Manager. Than the *project team* will be completed and the team roles will be assigned after assuring that everyone has a clear vision about the project and, if necessary, after training the team members for working together.

The project plan will be reviewed and detailed as much as possible and tasks and responsibilities will be assigned for each member of the team, as well as the relationships between them. It is very important to set clear *responsibilities* and *communication* lines and to establish the authority levels in order to avoid overlaps, misunderstandings or delays in completion of tasks.

Over the implementation, the Project Manager should ensure that the necessary *resources* will be released on time for each activity. He should forecast the possible risks for not getting the resources in due time and should develop strategies to overcome these problems.

An ongoing process during the implementation is *monitoring*. Monitoring focuses on periodic measurement of workplan progress and achievement of intermediate project milestones. Properly performed, monitoring provides current supervision and timely opportunities for remedial action (7). Factors to consider in determining the scope and magnitude of the project monitoring are:

- cost of the project
- previous experience of the implementing team
- manager's familiarity with and confidence in the implementing team
- complexity of the project
- potential for injury to the project due to delays in both reporting and responding

If monitoring is a method of ongoing review and measurement of the project to gauge its progress relative to its objectives and to plan continual improvements to both activities and management, *evaluation* takes a broad view of the projects activities, measuring the project's success and effects and showing what difference will the project make (8).

F. Champagne (6) has defined the evaluation process as being a judgement on any activity, provided service or project component. The judgement is always based on some criteria and norms (*normative evaluation*) – mostly used for project evaluation – or on some scientific methods (*evaluative research*).

During project implementation, evaluation can be done as internal and external audit (*operational evaluation*) which can propose ongoing corrections.

Usually, any evaluation is focusing on the three classical components:

Structure – the resources used by the project are evaluated:

- Human (number, level of competence, existence of incentives)
- Material (quantity and quality)
- Financial (budget)
- Characteristics of the responsible organisation: size, type, affiliations, degree of specialisation

Process – is focusing on the following aspects:

- Project planning (appropriateness and adequacy of activities)
- Project monitoring (existence of periodic and final reports)
- Project organisation (leadership, human relationships, responsibilities)
- Project stage related to established deadlines and budget

Ootputs / outcomes – is focusing on specific results achieved by the project as compared with established objectives:

- Provided activities / services in order to achieve the objectives
- Obtained indicators
- Intervention impact (follow-up of an indicator after the end of the intervention)

During the implementation stage *reports* will be required. Reporting allows Project Managers to share the findings of the project through monitoring and evaluation, requiring periodic documentation of the project progress. A stage report includes financial updates, implementation status report and periodic evaluations.

4. Completion

During this phase, the final project evaluation usually takes place. This is called a-posteriori evaluation and it measures the level of project objectives achievement, project impact on target population.

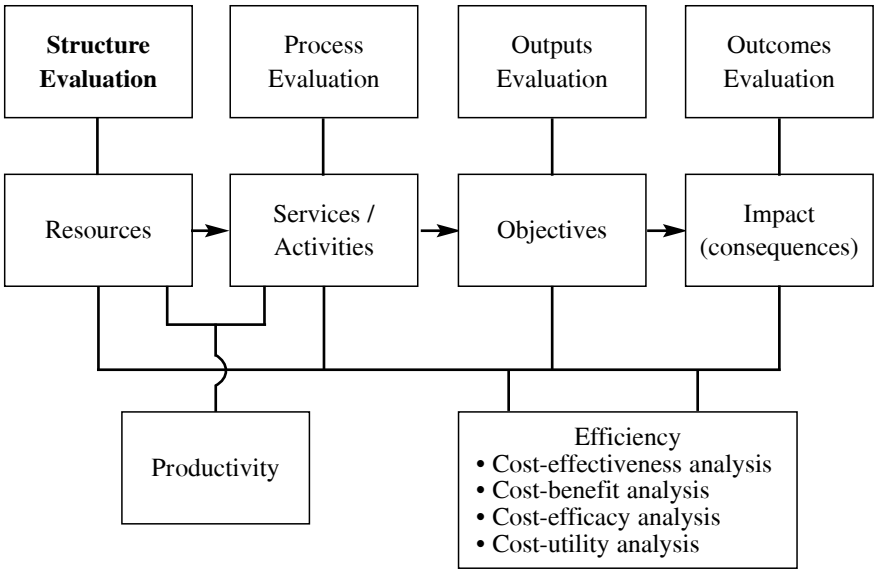
A more comprehensive evaluation (evaluative research) can also be done during this phase. It takes into account the *relationships* between the three components: structure, process, outputs / outcomes. For instance, a relation between different types / quantity of used resources can be estimated according to process or effects (outputs / outcomes).

Economic evaluation is the most appropriate tool for this purpose. There are two types of economic evaluation:

- *Productivity analysis* – establish a relation between the process (provided services / activities) and the resources used by the project (expressed as number of services per invested monetary unit, number of services per health professional etc.)
- *Efficiency analysis* – establish a relation between effects (output/outcome) and the resources used or provided services (both expressed in a monetary value)

A general framework of economic analysis was presented by R.Pineault (4) in Figure 5.

Figure 5. A general framework of economic analysis by R.Pineault



The most important document of the evaluation is included in the *Final Report*. This document usually describes the successes and failures of the project. The content depends on the project nature. The content will generally focus on expected results versus achieved results, as well as on the short-term and long-term impact on the target population.

The achieved results can be grouped as follows:

- *Physical results*
  - degree of needs attainment reported to a reference status
  - the achieved level of indicators as a consequence of project implementation
- *Socio-cultural results* (related to the improvement of quality of life, of the general health status, etc.)
- *Financial and economic results* (reduction of sickness rate for the active population, etc.)
- *Non-measurable results* (organisational change, capacity building, behaviour change etc.)

The final report will also describe the degree of goal/objectives achievement, the quality of norms and standards used by the project, procedures and criteria requested by the financing agencies, the quality of collected information. The conclusions will outline the encountered difficulties and, if possible, their generating causes, and will make recommendations on results dissemination. This document represents a valid basis for policy-making.

EXERCISE: Project Management

Task: Students will work in groups of 4-5 persons. Each group will be provided with the following model for a project proposal.

After each presentation during the lectures, the students will have to prepare every chapter of the project proposal according to the below model. At the end of the course, each group will present its draft of project proposal.

MODEL FOR PROJECT PROPOSAL

1. PROJECT NAME

2. EXECUTIVE SUMMARY

(Brief statement of the problem, short description of the solution, funding requirements, brief description of the organization and its expertise)

3. BACKGROUND

(Describe the context in which the project is developed; its relationship with other projects)

4. PROJECT JUSTIFICATION

(Brief description of the problem that requires the project. Facts and statistics will be presented in annexes. Show how the project would contribute to the problem solving or reduction and what would the consequences be in case that the project will not be done)

5. GEOGRAFICAL COVERAGE AND TARGET POPULATION

6. PROJECT DESCRIPTION

- Goal
- Objectives
- Action plan
- Detailed schedule (use a Gantt Chart)
- Detailed budget

7. EXPECTED RESULTS

8. MONITORING, EVALUATION AND REPORTING

(Use indices as much as possible)

9. ARGUMENTS TO THE SUCCESS AND POSSIBLE RISCS

(*feasibility, sustainability etc.)*

10. SUPPORTING MATERIALS

(ANNEXES: full description of the organization, CVs for the team members, Recommendation letters, articles, statistics, documents that could support Project utility, feasibility and sustainability)

References and Recommended Readings

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Planning and Programming of Health Care**
Module: 2.12	**ECTS (suggested): 0.25**
Author(s), degrees, institution(s)	Associate Professor Dr. Kancho Tchamov, PhD, MPH Faculty of Public Health Medical University - Sofia
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Keywords	public health, health care planning/programming, health caremanagement, goals, strategies, objectives, financial planning, monitoring, evaluation, planning team
Learning objectives	Applying the content of this module the student will be able: • to identify the determinants and the subsequent steps in the health care planning process; • to implement the public health planning/programming methodology at institutional, regional and national level; • to apply financial planning and budgeting technologies as a part of the overall planning/programming process; and • to monitor and evaluate health care plans/programmes.
Abstract	Health care planning and programming are future oriented processes aimed at defining strategies, activities and resources needed to achieve desired goals. The planning process consists of series of steps for accomplishing a set of targets to make the vision a reality. An experienced manager at any level of an organization should monitor the changes in the internal/external environment and the strengths and weaknesses of the planning design in order to increase its implementation effectiveness. Health systems have the objectives to improve health, to respond to people's expectations and to provide financial protection in cases of ill health. The careful and responsible planning as part of the managerial process, whether undertaken by government or by private bodies, often under general rules determined by government has a pervasive effect on all the workings of the system. The presence of planning and implementation competences among the executive and field staff in the health system is an asset to the achievement of the desired final results.
Teaching methods	Lecture, individual work, discussions, group work
Specific recommendations for teacher	This module should be organized within 0.25 ECTS, out of which one third will be under the supervision of teacher and the rest is individual student work. After the introductory lectures the student should become familiar with the steps of the planning technology and should start preparing a pilot plan/programme of a health establishment or a regional programme for achieving specific health care objectives or for reducing existing health problems. Results can be presented and discussed in groups.
Assessment of students	Presentation or essay discussing the elaborated pilot plans/programmes, tests.

PLANNING AND PROGRAMMING OF HEALTH CARE

Kancho Tchamov

A comprehensive planning process provides the structure and the subsequent steps for implementing a programme, serves as a guide for the effective use of human, material and financial resources, and at the same time creates a common understanding of programme goals and objectives among the programme implementation team. Many perfectly feasible and well financed projects fail to achieve the expected final results mainly due to the lack of full commitment on behalf of the senior staff and due to the lack of planning and implementation competencies among the executive and field staff.

The most important components of an effective programme/project are a clear vision of the future and a well thought out detailed plan describing the steps that must be taken today, next month, and the years to come in order to accomplish the targets set and to make the vision a reality. Although the planning process consists of a series of steps, it should not stop once the plans have been prepared. An experienced manager at any level of an organization should be continually on the watch for changes in the external environment and should be aware of the strength and weaknesses of the programme, ready to introduce adjustments in order to increase the effectiveness of the programme (1,2).

Planning is a future oriented process which allows a close look at the goals of a concrete organization or a programme/project aimed at defining what strategies, activities and resources are needed in order to achieve the desired goals. Plans therefore answer the following questions:

- What are the programme / project trying to achieve?
- What is the present status of the organization?
- Where the organization wants to be in a period of 2 – 5 years?
- How it is going to get there?
- Who is going to get the job done?
- How will an institution / organization finance its programme?

Planning thus covers a wide range of tasks. Both the setting of long-range

goals, strategies and the detailed activity planning for the immediate future are part of the same process. The annual work plans and budgets should usually be based on long-range goals and strategies but developed in a greater level of detail. Critical for any programme's success is the involvement of the senior as well as the junior staff in the planning process. An effective planning process can create a good proposal that could easily convince potential founders of the competence and the implementation abilities of an institution's abilities to design and implement a successful programme. Managers who possess effective planning skills have better chances to find additional funding, could have better control over their resources and could more likely achieve their objectives (3,4).

1. Specific issues related to the planning process

Building up rational plans for preparing and implementing well-organized programmes require to meet successfully the following realities and challenges related to the organization of the planning process:

Planning defines roles and responsibilities – plans define who is responsible for what; they set measurable objectives for a programme/project; the division of labor makes the team members accountable for the implementation activities and the achievement of objectives.

Planning challenges the existing situation – planning is a prospective activity which usually aims for improvement; it is expected to introduce appropriate changes in a program's environment which often require new strategies and new implementation technologies; the planning process puts the accent on the organization's interests rather than on the personal interests; planning is closely related to changing the existing environment.

Planning is a team exercise involving different levels of staff – successful planning activities are performed by a team involving key staff members in the planning process; the composition of the planning group includes representatives of all departments of an institution or a programme, all key activities and groupings; the team members should share a common vision and should be motivated to contribute to the success of the designed programme (5).

Planning requires the consensus of key staff – many key issues relating to organizational strategy may result in conflicts which need to be managed so that final planning decisions can be productive; consensus planning needs experienced facilitators who consider that disagreements are constructive as long as they do not degenerate into personal attacks; the involvement of specialists with different professional background depend on the planning goals

and the type of the planning process; staff at all levels should have the possibility of making their views known to the planning team and should be kept informed about the issues discussed by the planners (6).

Programme planning is a time consuming business – in many institutions managers and staff underestimate the fact that planning is a time consuming exercise, leaving little time for their daily responsibilities and for the concentrated effort planning requires; preparing in advance a schedule for the planning meetings and an implementation schedule is helpful for a well organized planning process; organizing „staff retreats" moving to a different physical location for the planning exercise sessions can be a rational decision (7).

2. Preparing a plan - steps in the planning process

Developing a plan requires that the new programme under consideration be broken down into smaller parts to determine which activities must be completed when and by whom in order to achieve the planned objectives. A completed plan provides the structure for implementing the programme, serves as a guide for the effective use of human, material and financial resources, and creates a common understanding of programme goals and objectives for the planning team.

When you start preparing your plan, first you have to identify the need and the demand for health care, and then to determine how to meet them for the specified target groups. This is a process containing the following steps:

- Stating the mission, or purpose of the organization/programme,
- Analyzing the external environment,
- Assessing internal strengths and weaknesses and external opportunities and threats (SWOT analysis),
- Establishing goals,
- Selecting activities for each objective; developing detailed work plans,
- Preparing a financial plan,
- Introducing a monitoring and control system.

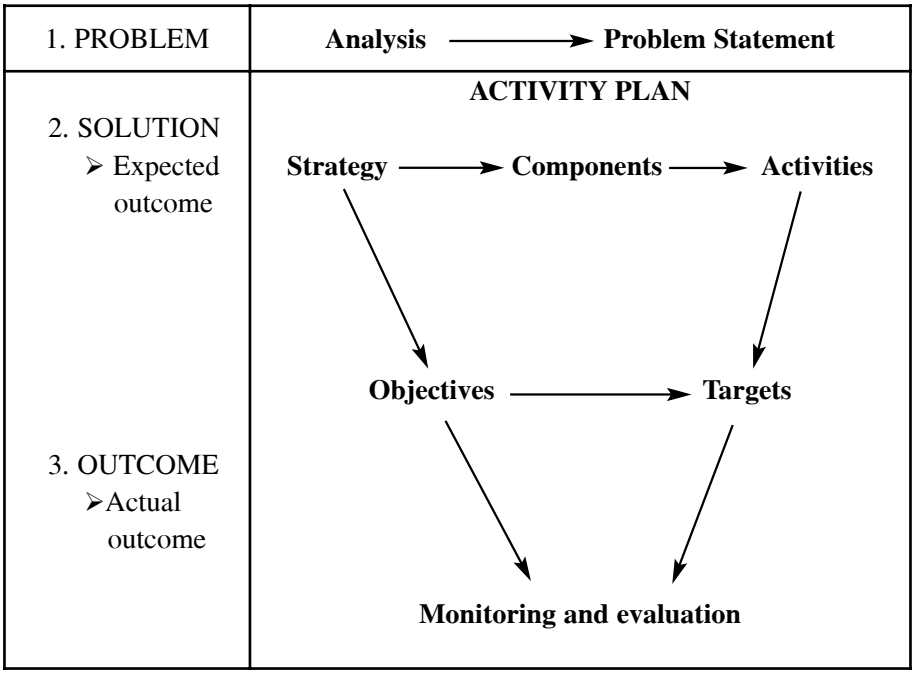
2.1. Stating the Mission (problem statement)

Stating the mission is the first step when preparing an organization's plan. Usually it is a general statement for the organization „per se", about its vision, purpose and values. On the other hand a programme or a project should be created to respond to community defined needs or problems. So the first part of the plan should justify the need for the programme. This part of the plan contains the following two sub-sections:

The problem statement – contains a description of a specific problem which should be solved or reduced by the programme/project. Some baseline information should be presented that helps explain the problem such as: the nature, scope or severity of the problem; geographic area, demographic, health characteristics of the population; availability of health services (primary, secondary, tertiary etc.), health personnel, financial resources etc.

The proposed solution – should contain a general explanation of the intentions and the design of the programme, stressing the important methodological aspects – most appropriate to address the described problem. The programme design should include: the approaches chosen for solving the existing problem; the expected positive results; sources of support now and in the future as well as the participating partner organizations/institutions; strategic alliances etc. (8).

Figure 1. Stages of the mission statement



2.2. Analyzing the External Environment

Analyzing the external environment is the next step that relates to the organization's mission, already defined in the mission statement. In general there are three main aspects that should be included in the external environment analysis:

- Collection of information data related to the programme/project from statistical sources and publications.
- Structured and informal interviews with administration officials/managers from ministries, municipalities, major donor organizations, NGOs and private sector.
- Guidlines and summary of the main findings compiled in an information paper prepared for the planning team (1,2).

When conducting the environmental analysis one should consider the possible information sources and the *necessary* information data relevant for the specific programme/project. In general terms the necessary information for conducting the external environment analysis may include:

- Macroeconomic data
- Data about the geographic and climatic conditions
- Demographic and health indicators
- Socio-economic information
- Health services information (outpatient and inpatient facilities, human resources, financing etc.)
- Policies and regulations
- Existing plans, intervention programmes and research projects in the health and social sectors etc.

2.3. Conducting the SWOT Analysis

The next step of the planning process is to conduct a SWOT analysis in order to identify and assess the strengths and weaknesses of the organization or programme as well as the opportunities and threats on the bases of the information gathered within the frames of the external environment analysis (9).

Table 1. Components of the SWOT Analysis

	Positive	Negative
Internal	Strengths	Weaknesses
External	Opportunities	Threats

The first steps of the SWOT analysis are aimed at defining the internal strengths and weaknesses of the programme or organization in respect to its management, programming and financing capabilities. A planning team should consider the items listed bellow and should decide whether the answers reveal strengths or weaknesses. The analysis of strengths and weaknesses of the programme/organization should cover the following management areas:

Analysis of management capabilities – determining subsequently the strengths and weaknesses in areas such as: organizational structures, planning, coordination, staffing, supervision, training, monitoring and evaluation procedures and systems, management information system, material resources management etc.

Analysis of programming capabilities – defining the potential capabilities of the organization/programme: to provide high quality medical services, training or education; to increase its efficiency; to provide grounds for improved patient satisfaction etc. This part of the analysis should define the weak points in the programme/project. What are the reasons for these weak points? What are the strong points? What expertise potential of the programme team reliable? Are there activities that could enhance the programme/project under consideration due to the lack of human or financial resources?

Analysis of financing capabilities – analyzing the financing capabilities one should give answers to questions such as: What are the programme's/project's current sources of financing? What is the self-financing part of the project? How stable are the financial sources? What changes in the external environment are supposed to generate more revenues? Where one can cut costs for the programme? What level of community or donor financial support does the programme enjoy etc.?

The second group of steps in the SWOT analysis is to focus on the process of translating the environmental analysis into opportunities and threats. Concretely one should identify those points that create opportunities for the programme and those that pose threats or obstacles to the performance or implementation process. This part of the SWOT analysis is usually carried out in a brainstorming session of the planning team. The analysis of opportunities

and threats can explain past performance problems and failures and highlight the opportunities and threats that could possibly affect the process of achieving one's goals.

2.4. Establishing Goals and Objectives

Selecting goals

A well-designed programme/project should have programme/project related overall goals. They define in general terms the long-term changes that will be the final result of the respective programme as outlined in the problem statement. Normally one or two general statements describing the expected long-range positive results for the target population are sufficient to describe the overall project goals. Organizational goals usually define the internal changes and improvements that the organization/programme should make in order to achieve its goals. In setting goals one should make sure that the programme related goals do not exceed the available financial, material and human resources. Established goals should not over-extend the organization's ability to provide quality services and the work team potential.

Example of an overall goal:

The HEALTH 21 policy for the European Region of WHO has the following main elements:

- The one constant goal is to achieve full potential for all.

Two main aims for better health guide efforts towards this ultimate goal:

- Promoting and protecting people's health throughout the course of their lives;
- Reducing the incidence of and suffering from the main diseases and injuries.

Source: Health 21- health for all in the 21st century. WHO, Regional Office for Europe, Copenhagen, 1999, p. 224

Selecting objectives

For each overall goal developed by the planning team there should be several specific and measurable objectives. These objectives should relate to the problem statement and describe expected results achieved through changes in knowledge, behavior and attitudes of the population or the target groups. The objectives should be used to ensure that evaluations conducted later in the project will measure the results the project intends to achieve. The objectives stated should be: measurable and observable; related to qualitative and quantitative targets as much as possible; and indicative for the specific time periods for the completion of the programme (10,11).

Well formulated objectives should be:

Specific – concrete, avoiding differing interpretations
Measurable – quantifiable, allowing continuous monitoring and evaluation
Appropriate – relevant to the defined problems, goals and strategies
Realistic – achievable, challenging and meaningful
Time-bound – with clearly defined time period for achievement.

Selecting strategies

The next step at this stage is to select strategies for reaching the stated goals. The process of selecting specific strategies is aimed at defining the technology of reaching the desired final results. The planning team could in a brainstorming session come up with several possible strategies that could be evaluated in terms of feasibility, financial impact, projected costs and time perspective. Using the information collected during the external environment analysis the planning team can analyze the existing competition on site i.e. look at what other providers (institutions, organizations, NGO's) are doing. At the end of this step state the strategy the planning team has chosen. If the selected strategy has several components, state each of them.

Although at this stage a detailed final analysis of the cost of strategies will not be conducted it will be necessary to consider the financial implications of the proposed strategies. The planning team should roughly cost the strategies taking into consideration the recurrent as well as the capital costs.

Selecting activities for each objective

The plan of activities constitutes the core of the programme/project and should describe the detailed activities to be accomplished for each programme objective. A fully developed plan will contain listed a detailed set of activities to be carried out in order to achieve each objective. Staff members of the planning/implementation team should be assigned to each activity, being kept responsible for controlling and carrying out the activity. The activity plan is supposed to provide the programme/project team with a clear picture of their responsibilities and activities during the project implementation. It can be divided in two parts:

Selecting detailed programme/project activities

Under each objective all the activities necessary for the fulfillment of each objective should be listed. The description of the activities should explain concretely how each of them would contribute to the achievement of pro-

gramme objectives. A staffing plan of the programme/project together with job descriptions for each post should supplement the activity plan. This section should contain: a description of all the activities to be carried out that answer the questions „what, where, by whom and when"; a description of the management systems (i.e. supervisory, information management, human resources and financial management) designed to support the activities listed; partnership activities etc.

Preparing programme/project activity timetable

A complete activity timetable is a condensed summary of the main project activities in their planned chronological sequence. It is a detailed description of the time-span in which each activity should be performed and of the team members responsible for the implementation of these activities. The programme activity timetable is an important implementation tool and should be used for monitoring the activities and the short-term results; for keeping the planned implementation on schedule; and for managing the programme's resources. A project activity timetable developed at the start of the project can be periodically updated and referred to by project staff on regular basis. It is helping programme planners and supervisors to integrate and coordinate their work, to monitor and evaluate the progress of the interventions under way.

It is useful to specify when it is aimed to start each activity. For each task or activity listed, consider who will be responsible either for doing it or, in some cases, for making sure that it is done.

Critical elements of the programme planning process

The following four areas of critical importance should be considered by the managers in order to develop a successful plan namely: procurement of equipment and supplies; training; service delivery and sustainability.

Procurement – the plan should include a procurement section supposed to list the types of supplies, equipment and materials necessary for the project. Tender procedures should be foreseen for the procurement of costly commodity supplies. A system for logistics management with record keeping and reporting systems should be worked out for the distribution of supplies to service points.

Training – the plan should contain a training programme for the implementation team as well as for the target population. This section should focus on: the programme content; the participants' background; the criteria for selecting the participants; the resource persons and the topics to cover; logistics plan etc.

Service delivery – if the programme/project foresees the creation of new health services or expansion of existing ones, the planning team should provide detailed information on any programme activities necessary to support the implementation plan. They may include: the replacement of existing equipment; maintenance contracts; renovation or reconstruction of service facilities; follow-up activities etc.

Sustainability – the important issue of sustainability is related to the capacity of the organization/programme to cope with the future changes in the external and internal environment. The ability of a programme to attract external funding or to generate income and develop self-sufficiency are the ways to establish financial sustainability. A description of the activities that will generate income and the ways that income will be used should be included in the plan.

2.5. Preparing a Financial Plan and a Budget

After selecting among the possible strategies, the planning team members make approximate estimates of costs against the revenues to determine their feasibility. While preparing a financial plan one should: analyze current and potential sources of revenue and expenses for the strategies chosen; assess whether the expected revenues will cover the expenses; monitor and revise activities to ensure the financial stability of the programme; prepare detailed estimates of revenues and expenses.

The next step undertaken by the planners after defining strategies, objectives and activities is to prepare a detailed year-by-year budget and a summary budget for the life-span of the programme/project. This detailed estimate or a summary budget is the financial plan. Once the financial plan is completed, the planning team can draw up a work plan and budget for the first and for every subsequent year. The budget will be based on the financial plan and will describe in much greater detail sources and amounts of revenues and expenses for the year to come (12).

In order to prepare the detailed budget one should carefully examine each programme activity and define the costs that are associated with its implementation. All costs will then need to be sorted into budget categories. The first draft of the budget should contain only direct programme/project costs, e.g. costs which are directly associated with specific project activity. Each item listed in the budget should be clearly identifiable in the activity plan.

Sample budget categories

There is no single correct way to develop a budget. When preparing a programme - budget, check your organization's budget categories and the types of costs included in each category. The categories listed bellow, provide a basic guide for developing and organizing a programme budget.

• Salaries and wages - This category includes the sums to be paid to project personnel for salaries and wages. Salaries are generally paid on a monthly or annual basis, while wages are paid on an hourly basis. In a budget each position should be listed with its title, the amount of monthly or early salary, the full or part working time and the hourly wages to be paid. Salaries and wages under this cost category should be planned only for employees of the programme/project.

• Fees - This category includes individuals who are not legal employees, such as short-term consultants and those hired under contractual agreements such as auditors, lecturers, researchers, evaluators etc. This category also includes honoraria paid for professional services rendered. The type of service, the individual performing the service and the cost of the service should be listed in the budget.

• Benefits - This category includes all expenditures for benefits in correspondence with the existing labor legislation in the country and the approved policy and practice of the programme. Benefits should be included only for persons listed under „Salaries and Wages" if the local laws does not mandate other types of entitlements.

• Travel and associated expenses - This category normally includes regular and customary travel associated with the activities of the project. These costs may include travel for supervisory visits, staff meetings, outreach and field visits.

• Supplies and equipment - Office and medical supplies, commodities and equipment to be purchased should be listed in this category. The cost of each piece of equipment and commodity should be shown.

• Education and training - The expenses related to this category refer to the costs of having participants in the programme attend specific training activities such as workshops, courses, seminars or conferences. It includes all expenses for tuition, training, fees, conference registration fees, travel costs, per diem, books and others.

• General administration - All expenditures that are not an issue of contractual agreements can be listed in this category. They include postage, freight

and shipping insurance, photocopying, printing, telephone, faxing, utilities, bank charges, publications, vehicle registration, employment advertising and other customary administrative costs.

• Purchased services - This category refers to long-term contractual services or agreements with institutions. For example building rental, maintenance contracts for equipment or vehicles, long-term leases on equipment or vehicles, advertising or promotion services that are of major importance for the project.

• Unforeseen costs - They include costs that do not fit into the above-mentioned categories. Such costs could be induced by: changing price and/or exchange rates, indirect cost rates etc. which can be listed here.

There are four types for funding programmes or projects namely: entirely government funding; donor funding; funding through generated revenues; and mixed type of funding. In drawing up financial plans one should distinguish between the different types of funding since the reliability of each source is different.

The planning process with no doubt will vary according to whether the organization or the programme is situated - in the public or in the private sector (13). A sample of a planning schedule is presented in Table 2.

Table 2. Steps in programme planning – sample schedule

Steps in Planning	**Participants**	**Time Needed**	**Dates**
Mission statement	Top and mid-level management	Three-hour meeting	January 14
Environmental Analysis- Report	Consultants and technical staff	Data collection Four Weeks	Jan. 14 - Feb. 14
SWOT analysis			
Formulating long-term goals			
Defining strategies and objectives			
SWOT analysis			
Preparing financial plan			
Departmental objectives			

Setting targets			
Preparing work plans			
Preparing annual budget			
Discussion and approval of departmental plans			

3. Programme monitoring and evaluation

Monitoring and evaluation plans of programmes/projects should be included in the initial programme design. The monitoring and evaluation process should be base on carefully selected indicators appropriate to the social, economic, health and information realities and possibilities.

3.1. Monitoring

Monitoring is a process by which programme activities and the programme-budget are regularly reviewed. Monitoring helps to ensure that the activities planned in the work plan are being completed and that the costs are in line with the budget provisions. Financial monitoring enables the project team to: control the rational spending of the budget; to verify that the team leadership's financial decisions are being followed; and to define whether budget revisions are needed. Monitoring of implementation and evaluation of effectiveness and impact normally take place at two levels: the policy making level; and the managerial and technical levels. Both levels should be interlinked (14).

In monitoring programme implementation it is important to use as reference points those objectives and targets that have been set as part of the process of formulating programmes and designing the health system. It is particularly important to monitor whether priorities are being adhered to, realizing that these may have to be implemented progressively. Indicators are then selected that can measure change toward attaining the objectives and reaching the intermediate and final targets (15). A monitoring plan should include at least the following:

- Creating a monitoring team which to include programme/project personnel who will be assigned the task to monitor the programme development, programme management and financial activities;

- Control over the timely monitoring procedures and their organization;
- Development of criteria to be used for monitoring the programme activities;
- Development of monitoring protocols.

3.2. Evaluation

The evaluation of a programme/project is a process of critical assessment of the degree to which the entire project or service components fulfill stated goals. It is important to have a plan for assessing project achievements during and after the implementation of a programme/project. The evaluation of a programme should analyze: the implementation process – referring to whether the planned activities were carried out and completed; the outcome - outcome evaluation often require a long term monitoring of structures, activities and staff performance; and the impact – e.g. the long term effect that the project had on solving the target problem or on the target population. Developing the evaluation section of the plan will make known in advance what elements of the programme will be evaluated, how and when the evaluations will take place. The scope and the content of the evaluation technology (i.e. what and how programme results should be measured) will help strengthening the team motivation for reaching the objectives of the project. In general terms an evaluation plan should include:

- sets of evaluation criteria developed by the planning team
- description of the evaluation technology used
- information collection and processing
- a reporting system

The development of monitoring and evaluation criteria should be based on the use of appropriate indicators. The indicators to be used can be grouped into the following five categories:

1. health policy indicators;
2. social and economic indicators;
3. indicators for the provision of health care;
4. indicators of health status and the quality of life, and
5. performance indicators.

At present many health care planning decisions are based principally on values and resources, i.e. opinion – based planning/programming; insufficient attention is paid to evidence derived from new information sources or to evidence from research findings. Nowadays as the pressure on the resources allocated to health care increases, there should be a transition from opinion–based planning to evidence-based planning decision making, adding sufficient evidence to this process. The management skills necessary for health care planning/programming in the 21st century will require: the planning decisions to be made explicitly and publicly; and the enough competence of those involved in planning exercises to produce sufficient evidence for efficient decision making (8,11).

EXERCISE: Planning and Programming in Health Care

Task 1: Students should use the recommended readings to increase their knowledge on the health care planning and programming technology, and the implementation of the subsequent planning steps in virtual and real situations. Small groups' planning exercises will be assigned aimed at elaboration of health care plans/programmes for pre-selected establishments at different levels of the health system. Results can be presented and discussed in groups.

Task 2: Students will be asked to prepare individually a comprehensive planning exercise for a health area close to their professional background related to curative, preventive or health promotive activities within the health care system. The selection of the problem areas and / or institutions as focal points of the planning exercise will be selected with the support of a tutor. The elaborated plans/programmes will be presented and assessed in plenary sessions.

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Recommended readings

1. Varkevisser CM, Pathmanathan I, Brawnlee A. Designing and conducting health systems research projects: Vol.1. Proposal development and fieldwork. IDRC, Otawa, 2003, p. 380.
2. Varkevisser CM, Pathmanathan I, Brawnlee A. Designing and conducting health systems research projects: Vol.2. Data analysis and report writing, IDRC, Otawa, 2003, p. 320.
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4. Cassels A. Guide to sector-wide approaches for health development. WHO, Geneva, 1997, p. 80.

Useful Internet Sites

- http://www.who.int
- http://www.who.dk
- http://omni.ac.uk

HEALTH POLICY

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Informed Health Policy and System Change**
Module: 3.1	**ECTS (suggested): 0.75**
Authors, degrees, institutions	Prof. Vesna Bjegovic, MD, MSc, PhD Professor at the School of Medicine, University of Belgrade Serbia and Montenegro Dr Bosiljka Djikanovic, MD
Address for Correspondence	Institute of Social Medicine, School of Medicine, Belgrade University Dr Subotića 15, 11000 Belgrade Serbia and Montenegro Tel: +381 11 643 830 Fax: + 381 11 659 533 E-mail: bjegov@EUnet.yu (Vesna Bjegovic) E-mail: boss@bitsyu.net (Bosiljka Djikanovic)
Keywords	Health policy, strategy, priority, management of change
Learning objectives	After completing this module students and public health professionals should: • increase their understanding of health policy; • understand the steps in the process of health policy formulation; • identify goals of health policy in a broader sense; • recognize main problems which could affect goals implementation and adopt recommendations for their solving; • explain the role and responsibility of key stakeholders in health policy; • identify similarities and differences between global and national health strategies; • realize the importance of skilled and comprehensive educated manager for implementation of health system changes, as well as their monitoring and evaluation.
Abstract	The modern health policy in its broader sense is striving towards a continual process of the population health improvement, through implementation of goals and priorities. Principal actors concerned for health policy are the government, ministry of health, health providers, health care consumers, health insurance and the general public through governmental and non-governmental organizations. For successful implementation of health policy, the number of established goals and priorities must be reasonable and wide consensus between interested groups should be achieved. The process must be followed by continuous monitoring and evaluation. The recommendations for the health policy changes refer to redefining roles of the state and the ministry of health, providing for the decentralization process at all levels, the regulation of the privatization process, sustainable financing of the health care system, the application of modern management at the system and institutional levels, the development of health information system as a support, and education of managers in this field.
Teaching methods	Teaching methods include lectures and small group discussion. Teacher should advise students how to use Internet source in preparing exercise - comparing health policy indicators.

Specific recommendations for teacher	It is recommended that the module should be organized within 0.75 ECTS credit, out of which one third will be done under supervision, while the rest is individual student's work. Teachers should be familiar to give examples of specific issues following the policy cycle.
Assessment of Students	Multiple choice questionnaire and quality of seminar paper (or oral presentation) will be assessed.

INFORMED HEALTH POLICY AND SYSTEM CHANGE

Vesna Bjegović, Bosiljka Đikanović

A policy is a guiding principle or a plan of action agreed to by a group of people with power to carry it out and enforce it. As a discipline health policy has its roots in political science – especially public policy – which is based on sociology, law, economics, decision theory, operational analysis and history (1). Public policies are aimed at the whole population or at specific, target groups and can be created by all levels of government as well as by institutions such as school boards, hospital workplaces or community organizations. Public policies are made through a process involving citizens, government officials, an elected officials who, ideally, working together to set an agenda for the common good. Policies shape our daily lives by regulating such things as where and when citizens may use pesticides, where we can or can not smoke, which medications and treatments health plan will cover, what is safe environment and so on. Policy making process is not something that takes place only among the most powerful in society. In countries with democracy public opinion and actions of interest groups become very important. One of the key functions of public health professionals is to influence and shape policy decision at all levels for the benefit of the population. Influencing policy at any level requires an understanding of public policy, how it is developed and what levers are available to influence the policy making process.

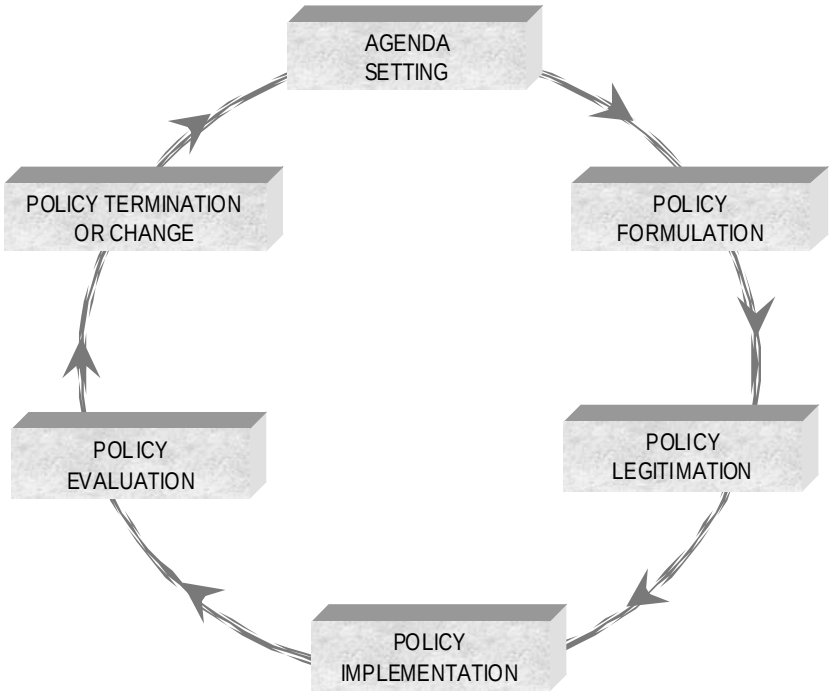
The health policy, „as a series of goal-oriented actions undertaken by authorized participants (usually government and state representatives)", is a relatively new domain of interest in professional groups even in highly developed countries (1). This interest is presumed to be a scientific response to an intensive development of the health system in the 60's and 70's of the twentieth century, an attempt to explain the reasons why the states tackle the actions aimed at proposing the course and contents of changes in the health system.

In pluralistic democracies, health policy becomes the focusing mirror for all other policies. It encompasses debates over money, access to services, health care quality, and outcomes. It also continuously reflects changes both in social context and in the very scientific base of medicine. There are no single issues in policies, and no clear boundaries; every political issue can ebb and

flow, and anyone can rise up overnight to dominate debate. Similarly, in health policy, every societal problem ultimately presents itself as a health problem. Health care can easily find itself affected by policies about an extremely wide variety of social issues. There are few clear boundaries. Social disintegration and economic trauma leads to unemployment, alcoholism, violence, drugs, teenage pregnancy – all become health care issues.

The modern health policy in its broader sense is striving towards a continual process of improving the population health (2,3). It represents the formal statements or procedures within the government and institutions by which the priorities and action parameters are defined as response to health needs, available resources, and various political pressures. The health policy can also be defined as a science of the health system management (4). It comprises ideology, tradition, and aspirations of authorities, while its basic purpose is to set up the path for the health system development, its strategy, the goals, priorities and means, as well as to establish a particular mechanism of evaluation for the realization of the priorities. Very often the health policy is described by using the Policy Cycle (Figure 1).

Figure 1. The Policy Cycle



The health policy is often followed by laws or other legal regulations, which define the incentives that enable the health services and programmes to

be provided for. As is the case with other policies, the health policy arises out of the systematic processes of creating the support for evidence based public health action, and it is integrated into community's endeavors, the political reality, and available resources (5).

In the last few years, both in developed and developing countries, efforts have been visible to reform the health policies through various changes relating to priorities, institutional – organizational structures, methods of financing, and health regulations. The health policy reform are decided upon by a governmental body, but the reform also affects the public and private institutions, it is inevitably occurring in the actual political framework, and it depends on the form of a given country's political system (parliamentary democracy, presidential democracy, one-party rule, dictatorship). The health policy as the foundation for the reform of the health system outlines the reflection of social values or ideals (such as accessibility to health care of high quality, education, government's responsibility), which determine the choices and actions. The process of formulating the health policy undergoes at least three clearly defined steps (6):

- Setting the goals and resolving the priorities (a process by which public attention is drawn to it and these are placed on government's agenda),
- Adoption of the policy (legislative process by which elected bodies decide upon a broad policy framework), and
- Implementation of the policy (a process by which administrators apply the policy, specifying numerous issues not covered by the health legislation).

The reformist interventions in any health policy imply the key role and partnership for the basic interest groups in a political structure: the state, health providers, health care consumers, health insurance and the general public through governmental and non-governmental organizations (7).

The state, acting through the minister of health, impels the managerial structures in all sectors to be oriented towards policies which facilitate health promotion. The partnership between the health and local authorities enables the local problems to be solved in the case both structures are directed towards the appropriate goals (8). Unfortunately, it is often the case that a health policy proves inefficient, for the lack of a clear strategy, or the goals and priorities adopted by all parties involved, and if these are created by the most powerful and influential groups, such as clinicians' »lobbies«, or by politicians outside

the health sector. It also happens that in the process of reform only the goals and priorities are changed, without their implementation and evaluation, while the health policy itself remains an instrument for both the actual ruling group and the opposition, or some informal centers of power and authority (4).

Health policy goals and priorities

The goals in the broadest sense represent the desired state of affairs toward which the activities and resources are directed, but which may not be achieved necessarily (9). Even though there is a tendency to quantify the goals, many distinguished authors point to a »virtue of vagueness« when setting up the general goals, and to the necessity of their constant reassessment (10). This is reflected in the fact that the health systems differ from one country to another, and even then most of them have similar general values and goals of their health policies (11):

- Availability of health care and equality of the consumers in the system – achieving equity in access (envisioning the existence of a minimum health care available to each citizen and an equal treatment for equal needs within the state/social health sectors);
- Material security of citizens (foreseeing that patients are protected from such health care payments which could seriously impair their incomes, that is, their contribution in the cost of health services is to be connected to their ability to pay);
- Macroeconomic efficiency (implies that the health care costs should be allocated an adequate amount out of the national income in order to secure certain level of health care for the population);
- Microeconomic efficiency (meaning that an improvement of population health should be maximized according to the level of resources invested in the health system, i.e., to achieve as much as possible with the allocated resources);
- Freedom of choice for the consumers (expects the freedom of choice among different providers to exist for the consumers of the health system); and
- Adequate autonomy for the service providers (implies the freedom of doctors to work in a way that they consider to be in the best interest of a patient), which is compatible to fore mentioned goals.

A characteristic of the stated general goals is that they are oriented to outcomes, and that they orient decision-makers onto outcomes, as opposed to former approaches when the goals, not so long ago, were rather oriented to expensive health care inputs (such as, for example, the number of newly provided hospital beds, or a larger sum of money spent on health services) (12).

Recognizing these general goals in determining the health policy most countries adhere to the recommended goals of international health organizations and the international community. Among those the most cited and, according to many authors, the most ambitious health policy is the one formulated by the World Health Organization »Health for all by the year 2000« and »Health for all in the 21st century« (13,14). The literature dealing with health policy also often cites "UN Millennium Development Goals", the health policy formulated in the United States as »Healthy People«, as well as the health policy of the European Union (Table 1) (15,16,17).

The World Health Organization adopted a resolution back in 1977 emphasizing as the main social goal for more than 190 countries members »the achievement of such a level of health for all people which would enable them to lead a productive social and economic life«, with an active participation of all people in the determination of health and in the development of a socially oriented primary health care. The dimensions of the European strategy »Health for All« initiated in 1980 referred to the equity of all people in the health system. They were oriented to health improvement, to active participation by an informed and motivated community in achieving health, to inter-sectorial cooperation, development of the primary health care according to the health needs of the population, and to the international health cooperation concerning the problems which surpass national frontiers (13). Relying on the indicated dimensions, the Regional Organization for Europe in 1984 formulated 38 regional targets describing how the present circumstances must be changed by the year 2000 in order to achieve health for all. Regional targets by the year 2000, according to the contents, are grouped into three spheres:

- basic requirements for health,
- necessary alterations (healthy life styles, healthy living environment, and an adequate health care), and
- support systems for health development.

Table 1. UN Millennium Development Goals (MDG)

1. Eradicate extreme poverty and hunger	• Reduce by half the proportion of people living on less than a dollar a day • Reduce by half the proportion of people who suffer from hunger
2. Achieve universal poverty education	• Achieve that all boys and girls complete a full course of primary education
3. Promote gender equality and empower women	• Eliminate gender disparity in primary and secondary education preferably by 2005, and at all levels by 2015.
4. Reduce child mortality	• Reduce by two thirds the mortality rate among children under five
5. Improve maternal health	• Reduce by three quarters the maternal mortality ratio
6. Combat HIV/AIDS, malaria and other diseases	• Halt and begin to reverse the spread of HIV/AIDS • Halt and begin to reverse the incidence of malaria an other major diseases
7. Ensure environmental sustainability	• Integrate the principle of sustainable development into country policies and programmes; reverse loss of environmental resources • Achieve significant improvement in lives of at least 100 million slum dwellers, by 2020
8. Develop a global partnership for development	• Develop further and open trading and financial system that is rule-based, predictable and non-discriminatory. Includes a commitment to good governance, development and poverty reduction - nationally and internationally • Address the least developed countries' special needs. This includes tariff - and quota-free access for their exports; enhanced debt relief for heavily indebted poor countries; cancellation of official bilateral debt; and more generous official development assistance for countries committed to poverty reduction • Address the special needs of landlocked and small islands developing States • Deal comprehensively with developing countries' debt problems through national and international measures to make debt sustainable in the long term • In cooperation with the developing countries, develop decent and productive work for youth • In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries • In cooperation with the private sector, make available the benefits of new technologies - especially information and communication technologies

Source: UN, http://www.un.org/millenniumgoals/

Such health policy has stimulated many European countries to formulate their national strategies and, in many cases, to set their own goals in order to improve health (12). The World Health Organization has recently reevaluated critically the achievements in the realization of the targets set for 2000 and Regional Organization has created a new set of goals for the health policy in Europe – »21 targets for the 21st Century« (14). This new health policy clearly promotes social equity, as well as definition for the key values and objectives. The European targets, 21 in number, rely on 10 global ones which may be divided into three groups (14) (the WHO European targets are presented at the WHO web page):

- Targets in relation to the people health outcomes,
- Targets in relation to health determinants, and
- Targets in relation to the health policy and sustainable health care system.

Concomitantly with formulating the targets for the European region, the World Health Organization also suggested some possible strategic guidelines and certain solutions for the implementation of national policies. For example, as for the health promotion, the projects and programmes with some positive experience are particularly recommended, such as »Healthy Cities«, »Health Promoting Schools«, »Healthy Hospitals« and similar.

After fifteen years of experience in designing, implementing, following, and evaluating the health policy, it is appraised that the highest achievements of this policy for health are strengthening the public health orientation through the health promotion and healthy life styles, healthy living environment, health care oriented towards quality and efficiency, and in a considerable improvement of knowledge about the creation of »the public health policy« (18,19). The public health policy is characterized by explicit care for health and equity in all spheres of politics, and by responsibility for influencing the health (5,18). The main goal of the public health policy is to create an environment which sustains and enables people to lead a healthy life. Such a policy makes healthy choices possible and easy for all citizens, and it is based upon an approach which promotes health, according to which the governments are ultimately responsible for the health consequences of their policies, and for their shortcomings, too. Adherence to the public health policy means that the governments are obliged to measure and report on their investments in health. Investment in health is a strategy to optimize the influence of public policy onto the health promotion (18).

However, questions are raised as to usefulness of formulating the precise goals as components of the health policy, and particularly of indicators

used in following their realization or failure (20). Therefore, the recent reviews of goals point that the efficiency of a health policy is highly dependent on the implementation which is divided into three levels:

- intention to define the goals on a political level,
- developed plan at the political level, and
- a plan for the implementation of goals at the practical level.

Development at a political level requires recognition of needs for an action and a political will for implementation. Some countries recognize this need for action more than others. Even when there is a political will to act and an agreement on the course of changes, the goals may remain unrealized. The experience of certain countries in the implementation of the formulated goals reveals the following recommendations (19):

- a wide consensus among all interest groups is necessary,
- the number of goals has to be limited rationally, for most of the national policies are focused onto five to ten goals,
- each goal must be founded upon evidence on efficiency, which is particularly difficult when it concerns the health promotion, and
- the goals must be conformed to available resources.

According to one of the World Health Organization's analyses of 1997, political responses in the process of the health system reforms in many countries throughout Europe can be observed as distributed into two categories: formulation of goals, and classification of specific interventions (21). The first group includes: change of the role of the state and market in health care, decentralization onto lower levels in public-state sector and towards the private sector, strengthening and greater choice for the citizens, and improvement of the role of public health. The second group comprises interventions classified according to achieved outcomes, differing the successful ones from those less so.

In the European Union the health policy lays particular emphasis on public health in regards to the goals, as is also recognized in the EC Treaties even in the Maastricht Treaty adopted in 1992 (17). Social character of the health systems in the European Union is based on the premise that „health care in not a normally traded good and access to it is a fundamental right" (22). Member States have stated, in the Treaties, that the organization and delivery of health services and medical care remains a matter of national competence. The driving force of the European integration process has been establishment of a single market. The European Commission, the European Parliament and

the Council of Ministers are the principal actors responsible for planning and implementing policy in the EU. This tripartite structure also ensures the process of health policy making based on the principle of subsidiarity. Subsidiarity is the EU principle which states that action should not be taken by the Community unless the objectives of the proposed action cannot be dealt with properly at national level. Sometimes, this is used by opponents of EU health policy to say that EU should not have any powers in public health field. This means in practice that a health measure can be declared illegal if it does not improve the internal market and consequently economic interests are given political priority over health. On May 1st 2004 the EU underwent the latest enlargement as 10 new countries joined it. This one is different from those that have gone before, particularly according to the level of development between the member states and will almost certainly have implications for health and EU health policy (22).

At present health and social policy in the EU is being developed in a different fashion, which follows expectations related to four freedoms (22,23):

- free movement of goods,
- free movement of persons,
- free movement of services, and
- free movement of capital.

Recent developments in the countries of the European Union show that, notwithstanding the globalization and creation of a unified European market, this was not subject for debate when the national health policies were reviewed, and the European Union itself has so far only had general recommendations for the health policy. Those general recommendations were formulated through goals referring to advocating the health promotion, to the prevention of certain diseases affecting the whole of humanity, to the pertinent mechanisms for the inclusion of the community and the strengthening of research in the field of public health, particularly the health care for certain population groups, such as the elderly, the poor, the refugees and Roma population. However, as a group of experts recently cited picturesquely, »the global economy (of the European Union) is sitting at the table, while health politicians discuss financing the hospitals and paying the doctors at national levels« (24). As an example, the patients in the European Union can now freely choose where to obtain their glasses or orthopedic appliances. The possibility of such a choice is reviewed as to the selection of hospital, which would have serious consequences in the sphere of financing the national health care systems, as

well as for the arrangements with hospitals. As joining of 10 Central and East European countries is happened, the health policy of the European Union will have to take into account the needs and expectations of their inhabitants.

Also, it is not only economy which is connected to the national health situation in the European Union. The countries of the European Union recognize the significance of other issues stemming parallel from the establishment of freedom of movement of people, goods, and services, such as ethical standards. For example, some countries forbid by their national legislation certain procedures in prenatal diagnostics, but they cannot prevent future parents from being informed about them in other European countries. Also, the growth of poverty, the new and old communicable diseases, emergence of resistance to vaccines, but also the sale of body organs and pharmaceutical products, point to the necessity of comparative research, particularly the health status, and increase the need for greater coordination among the European Union member states. Under the conditions of exceptional mobility, the national legislatures are facing potential inefficiency. Thus, the national health politicians in Europe will have to find balance between the standards required by their own public and what can be achieved through their national legislation.

It is assumed that the European Union would have to formulate more specific goals in this sphere, while it is certain that the European health systems would not be determined in a single centre, as it is the generally accepted principle that the health service, which is to respond to the consumers' needs, cannot be organized through »supra-national bureaucracy«. However, even the national legislation must be adapted to the change, and health politicians should take the environment in the neighboring countries into account (23). It is presumed that, beside the reviews of health policies at the political panels, such as the European health ministers' meetings, some broader analyses are also required, performed by multidisciplinary professional teams. One of the indicators of the growing interest among the professionals is the publication started in 1999 of a bulletin where information is exchanged and challenges recorded in the fields of national health policies in Europe (European Health Forum Gastein – Issues in European Health Policy, which is accessed free of charge on the Internet). Effective advocacy for health and health policy in Europe is also supported through the Open Method of Coordination, which facilitates policy reform by promoting mutual learning among Member States. The Open Method of Coordination gives a concrete meaning to the European social model, by helping to build consensus and to create a greater balance between the social and the economic dimensions in EU policy. This method includes:

- fixing guidelines for the EU combined with specific timetables for achieving their goals;
- establishing indicators and benchmarks as a means of comparing best practice;
- translating the EU guidelines into national / regional policies; and
- periodic monitoring, evaluation and peer review.

The Open Method of Coordination is a process in three stages:

1. A Political Agreement on common objectives,
2. Each Member States submits a national Action Plan, explaining how it proposes to pursue the objectives (use of common indicators, easily comparable, benchmarking and good practice), and
3. Follow up – Joint Report and corrective action used under the peer pressure.

After the national goals are set in any health policy, there remain other challenges which are related to their implementation and prioritization. It is necessary to understand the actual patterns of the population health status. Design and implementation of activities which are to lead to the realization of the goals require a high level of managerial skills in the sphere of public health. The following of progress requires acquaintance with the natural course of a disease. The crucial question is how much time does the achievement of goals take, and whether the set goals lead to any differences in health. The simplest answer to these questions is that it depends upon many factors, for there is no simple model for a health policy based solely on goals, just as there is no simple model of governance.

Measurement of progress in achieving the goals of each health policy is mainly determined by the nature of the set of goals which are to be measured, and in the European context the indicators suggested by the World Health Organization referring to the development of a health system founded on primary health care and on planning and managing the health system are most often used (13,14). As the external and internal environments pose numerous objectives to the health care system, a clear definition of priorities is an imperative as it secures monitoring and evaluation in the process of achieving the goals.

Changing the legal basis for health and health policy is ongoing process everywhere and in the European Union it could be recognized in the Convention on the Future of Europe (http://european-Convention.eu.int/). According to this document essential to ensure health is an objective of the EU and a shared competence of the EU and Member States.

The role of the state and the ministry of health

In all health systems the state has the role of a collective mediator between other system actors: population – the consumers, providers, those who generate resources, other sectors. Besides, it also performs a series of other functions, sometimes isolated ones, but more often combined. Thus, the role of the state in the process of the health policy development refers both to guaranteeing that the changes in the health policy would be adopted by all the stated participants, and to the implementation of those changes, particularly of those that are related to the process of centralization – decentralization, privatization, and financing the health system (21). At the same time, the national health policy in the process of reform is supposed to secure an adequate approach to defining the role of the state.

As can be perceived from the experiences of other European countries the role of the state goes beyond traditional measures of »command and control« and it furnishes incentives for the development of regulated market-oriented models of providing the health services. It is especially notable that the regulatory measures by the state are supposed to be more flexible and to temper through national legislation the multitude of differences (territorial, demographic) that often exist in democratic states. Effective regulation by the state, too, is to be reinforced by following and evaluation of outcomes, not by contracting certain inputs (expensive equipment, enlarged hospital capacities, and similar). Beside the state regulation, the health policy is to advocate the competitive state measures which are to provide for the process of active privatization, as well as for a competent supervision of contracting, and other market mechanisms by the state (24).

As for the responsibility of the state, it is considered that the basic one is the responsibility referring to securing the accessibility to the nationally guaranteed set of services for each individual. Besides, responsibilities of the state are also (25):

- national planning and supervision of the regional plans,
- incentives for offering the health care to vulnerable populations,

- to offer certain additional services out of the obligatory set of services which are financed outside the adopted model (e.g., outside the obligatory health insurance),
- to organize data collection on population health status and on functioning of the health care system, and
- concern for the programmes of continuous quality improvement – total quality management.

According to the London Institute for Health Sector Development, the future of a health ministry, as a representative of the state, is to be freed from operational duties so that it can concentrate upon the health in its broadest sense (26). In the public sector this would mean:

- the stimulation of activities which ensure that the financing process be connected to the needs of the health service,
- the work with partners in the development so that duplication and administrative burden of multiple projects would be avoided, and
- offering the national information on the quality, efficiency, protocols, data, and priorities.

In case of the private sector the role of the health ministry refers to:

- the control of the size of the private sector (too many providers means too much use),
- the registration and follow-up,
- the encouragement of self-regulation,
- the control of the expensive technology, and
- the contracting of services which are to be financed from public funds and which would have the adequate standard of quality.

The position of decentralization in the health policy

The issue of decentralization takes up a key position in the scope of measures of reforms of the health policy in most European countries, especially those in transition. The decentralization designates, in the broadest sense, transfer of authority and responsibilities from the higher to the lower levels of authority. The transfer of authority from the central administration to the bodies of smaller and local communities does not mean at the same time that the central administration would be deprived of all authority. On the contrary, it

would still retain important functions, such as legislative, financial, regulatory and other duties.

The most prominent goals realized through decentralization in the field of health care are the following (23):

- stimulation of improvement of offering health care services,
- better allocation of resources according to the consumers' needs,
- diminishing of inequity in the sphere of health,
- community involvement in the decision-making on priorities,
- faster and more adequate reaction to the consumers' needs, and other objectives.

Decentralization removes all those shortcomings that are ingrained in centralization, such as: inefficiency, slow acceptance of changes and innovations, delayed reactions onto factors endangering population health, susceptibility to political manipulations, and numerous other failings.

Decentralized institutions have multitude of advantages. They are more flexible than the centralized institutions and more effective in identifying the problems and prospects for their solutions. They generate higher morals and greater productivity. The decentralized structure also bolsters the partnership of health politicians with the citizens and local groups, and thus it also expands democracy in making political decisions concerning health at a local level. A successful decentralization requires specific social and cultural environments. Certain local administrative and managerial capacity is required most of all, as well as readiness to acknowledge several interpretations of a single problem.

The issue of decentralization is a very complex one, and when it is to be introduced the right measure has to be found. Any excess, whether it refers to total centralization or total decentralization, affects negatively the proper course of the health care process. Experience with the decentralization in many countries reveals that certain areas in decision-making should not be decentralized, and those are (21):

- the basic health policy framework,
- the strategic deciding on the development of health care resources,
- the regulations related to public safety, and
- the monitoring, estimation, and analysis of the population health status and of the health services offered.

Recommendation for the health policy changes

The recommendations for the health policy changes in the recent literature refer to:

- redefining the roles of the state and the health ministry,
- providing for the decentralization process at all levels,
- the regulation of the privatization process,
- sustainable financing of the health care system (elaborated in the section on financing),
- the application of modern management at the system and institutional levels (also elaborated upon in the section on health management),
- the development of health information system as a support to the health care system management (elaborated in a separate section), and
- education of managers in the health care system.

Redefined roles of the state and of the ministry of health

The states of countries in transition are supposed to have an important role in the whole health care systems, the one, however, which is quite different from the one that they have today, the one which is matched to the role the same bodies have in other modern countries.

In a reformed health care system, the state, through its authorized ministry, must be engaged in at least the following areas:

1. Adoption of documents at the government level on public health policy, i.e., the health promoting policy. The aims of such a document are to set up the health high on the priority list in the country, and also to undertake concrete activities thus oriented, with the health promotion approach. These activities do not involve only the health sector, but are obligatory for all the segments of a community that can contribute to health, or else endanger it. It is also necessary to define precisely the role of the non-governmental organizations, those directly or indirectly preoccupied with health promotion, while they can offer serious assistance to the governmental institutions in their all-encompassing interventions in the education for health.
2. Adoption of documents at the level of the health ministry on the health of the nation, which define the priorities in the health care system in the sphere of

health care, but also referring to the organizational forms. Such a document is to be conformed to the mentioned documents of the European health policy, being the strategic foundation for the formulation of specific objectives evidence based from research on the health needs, financing, and functioning of the whole health care system in the country. The specific objectives are to be furnished with a time frame for their achievement and a flexible process in which the change is tested locally, or in pilot environments before it is widespread all over the country (27).

3. Regulative – legislative role. Beside a number of regulations and laws decreed by the state, it is of utmost importance to regulate the private sector in the health care so that active privatization is defined.
4. Strategic planning aimed at the realization of defined goals of the health policy, especially to assure the guaranteed rights of citizens and their general interest in the health care.
5. Initiating and financing the strategically important programmes of health care (children health, family planning, health promotion programmes, prevention of spreading of some diseases, both infectious and chronic, health care for those not insured, capital investments).
6. Establishment of health institutions to perform the health care at the tertiary level and the rights stemming form it.
7. The control role, covering a range of duties at different levels and of different importance. Beside the noted monitoring and control over the legislative sphere concerning the performance of the health insurance system and the health institutions of all forms of ownership, it is also necessary to set up monitoring of the quality of work, the mechanisms for the accreditation of health institutions, both state-owned and private ones, then of the individuals in those institutions, either generally or for specific services. An important control role consists of formulating the assessment mechanisms for the introduction of new technologies (health technology assessment), as well as control of the use of highly specialized health care (utilization review).
8. Defining the strategy for the development of the health information system and its architecture (v. Section on health information systems).
9. Initiating the strategic research concerning the decision-making in the health care policy.
10. Foundation of the National Health Council as an independent expert-advisory body for the matters concerning the health care, made up of experts and renowned professionals in certain fields.

Providing the decentralization process at all levels

In a reformed health system a particular place is given to decentralization. Promotion of the primary health care as the foundation of the whole health system necessitates the obligation to transfer the bulk of authority from the central governmental bodies onto the local ones.

In a decentralized health system, the municipality and the city are to:

- Follow the population health status on their territories, and to propose and undertake the required activities.
- Adopt and carry out the programmes for the improvement of population health status on their territories which are not encompassed by the referential programmes at the national level.
- Provide for the realization of the public health activities on their territories which are not encompassed by the referential programmes at the national level.
- Adopt and carry out the programmes for the development of a healthy living environment which are not encompassed by the referential programmes at national level.
- Establish the health institutions the performance of which provides the realization of the legally regulated rights of the citizens in the field of health care (primary health care center, office of physician and dentist and pharmacy).
- Determine the fulfillment of prescribed conditions to start operating and affecting the health care activities in regards to personnel, equipment, premises, for the state-owned health care institutions whose founders they are, and for the health care institutions or other forms of health care activities in private property.
- Besides controlling the lawfulness of operation, they also perform the outer checks of quality of the health care offered in cooperation with authorized bodies and chambers at the national level.
- Secure the financial means in their budgets for the stated and other purposes in the health care system.
- This form of decentralization, including the one proposed in the Section on financing the system, would greatly contribute to constant improvement of the health care quality.

Application of modern management at the system and institutional levels

The health policy entails that both the philosophy of the management at the system and institutional levels is determined, and that the management of change be applied in the implementation of the reformist endeavors. In many European countries today it is almost unimaginable that the process of decision-making is conducted by those individuals who do not possess management responsibility and professional managerial skills.

For the complete system of management of the reform process it is of utmost importance that no mistakes which were recognized in former reforms in the Central and East European countries are repeated. Most often those mistakes were reflected in disregarding the necessity to have a qualified and efficient management, and also in the engagement of foreign experts without proper knowledge of the local circumstances, or the socio-economic and political systems in those countries. Nevertheless, the good characteristic is the recognition of the partnership with high developed countries manifested in a long-term support for the programmes of »educating the educators« for management and organizational development (28).

It would be advantageous if the modern system and institutional management, conditioned by permanent changes in its environments, especially so in the process of reform, is based on the philosophy of management by objectives and the total quality management.

Management by objectives, the concept introduced first in industrial company by Peter Drucker back in the '50s of the 20th century, can be often found today applied onto the health care system. It is a process in which both the superiors and subordinates identify general goals jointly, defining the field of responsibility while achieving the expected results, as well as criteria upon which the individual contributions for the accomplishment are followed and measured (29). Attaining the goals defined in advance is the central process of each management. General goals of the health policy in the process of reforming have to rely on mandatory documents of the international health policy, while establishment of specific objectives must be based upon evidence from national health system, and it is to involve step by step in defining the priorities. It is beyond question that at the system level all interested parties must participate in this process, particularly the general public, for it enhances readiness, motivation, and endeavors in introducing the change.

At the institutional level, the goals can have an enormous influence onto the participation of the employees in management, which is extremely important

for the success of any health policy. The goals of the institution should favor knowledge, public health orientation, and the quality of operation, by which greater participation can be expected, as well as higher responsibility of the doctors in the process of management. The main characteristics of this process are:

- The manager and the employees understand and have a mutual consent on main duties and responsibilities of the personnel;
- The employees set short-term and sometimes the long-term objectives in the execution of their work together with the management, which secures that the objectives be consistent with the organization's goals;
- The manager and the employees agree upon criteria to be used for the measurement and evaluation of attained results;
- Periodically, managers and the employees evaluate the progress in attaining the objectives and they carry out the alterations of the objectives in case the circumstances require them;
- The manager has an active role in all coordinating mechanisms and ensures resources indispensable for the realization of the objectives, and
- The estimation consists of the measurement of outcomes of operating and in identifying the achieved objectives in regards to timetable and previously established criteria.

The next important instrument of the new health policy and health care system is the total quality management – the principle of doing business which holds the improved effectiveness, efficiency, and proper reacting to consumer's requests as its basic characteristic. It is realized through active participation of all the employees within the organization in the process of improved services' operations. The crux of the total quality management is the realization of business and organizational excellence (30).

The nature of managing the quality, as well as the mechanisms for introduction of the total quality management programmes (the synonym is the term: »continuous quality improvement«) into the health care system, due to its complexity, differs considerably from those encountered in other business and industrial fields (31). The health institutions themselves are known to the theory of management to be the most complex organizations with the most complex management, while the modern hospital is on top of the list of complexity (32). There exists a triple distribution of power, responsibility, and authority (board of managers, director, and doctors), an extensive differentia-

tion and specialization of operating abilities is evident, and work duties are performed by a great number of participants who differ according to the degree of education, training, and functions.

Therefore, the main characteristic of the total quality management in the health care system is that it places the system, i.e., the institution to be its basic unit for analysis, and that it emphasizes the quality improvement by focusing onto prevention, not to correcting the poor quality, then onto the consumers of health care services, onto the system and its processes, and onto the organizational culture (33). In that way both the quality and productivity are enhanced, while expenses are diminished.

At the national level, the total quality management is focused onto the measurement of performance and constant improvement of the quality of the whole health care (25). This entails establishment of the national goals of performance in relation to the chosen specific fields of quality, setting up the minimum standards for accessibility and quality, support to the research, assessment of technologies, development of tools to measure outcomes, evaluation of the impact of reform onto the quality of health care, the yearly reports on performances in the health care system, recommendations for the yearly alterations in the measures of quality, and establishment of five-year priority list, as well as usage of the national network of regional centers for collecting data regarding the quality health care. The national programme of quality improvement is to be supervised by an advisory board at the level of the ministry of health.

The main processes of the total quality management at the institutional level are (34):

- transformation of the organizational culture so that it be completely directed to the beneficiary and his or her satisfaction,
- stimulation of the employees at all levels to improve the organizational process,
- integration of the system and methods of support in order to motivate and reward the employees according to the quality and productivity of their work, and
- engagement of systematic and institutional managers in cultural transformation, decentralization in decision-making, stimulation of the employees to approach the organizational changes management in a systematic way.

Therefore, for example, a hospital with the total quality management programme sets specific objectives for the quality, selects a number of priori-

tized fields (projects) for the improvement of quality, includes in the description of work for each employee the activities related to the quality improvement, plans time for those activities, secures the necessary resources (financial, and others), and provides for the compulsory education of the team members to be formally involved in the quality improvement activities.

In the course of this process the »managers of quality« in the health care system and the health institutions are mentioned frequently, and as the critical factors which characterize the managers of quality the following are prominent: ability to motivate, to find the optimal stimulating structure, to create confidence, to delegate and decentralize. The wish to respect the will of the consumers of health services is important, just as to listen to the associates and to have a sense for subtle dimensions of interpersonal relations. A manager has an important role also as the creator of the image and vision in the programme of total quality management (35). The management is to be a catalyst in the process of permanent quality improvement, and the quality is part of the values created by all employees in the health system. The outcomes are important indeed, but the main emphasis lies upon the analysis of the process and in its improvement (36).

There are various barriers in the organizational structure of the health system that have to be surpassed in order to make the total quality management programme efficient. One of the most prominent is to solve the existing conflict between a management and the professional autonomy (29). Physicians with their professional autonomy have a powerful role, as they are responsible for the basic activity of the institution – providing of health services, and for the majority of decisions that create expenses. The doctors, privileged by their medical knowledge, also have the greatest organizational potential, as the nature of their profession implies a broader field than just clinical diagnosis and treatments, thus making them strive for unrestricted power over the economic and social aspects of their work, besides being of authority over the clinical aspects of diagnosis and treatment. However, as most often they are very little interested in affairs of the institution outside the domain of their own profession, the doctors contribute to organizational flows. Despite their eminent knowledge of medicine, in reality most doctors know little about the surroundings they work in, as they spend most of their time working with patients or trying to gain more knowledge on their own. This phenomenon is recognized as the separation of professional autonomy from the institutional interests, which interferes not only with the total quality management, but also with the programme of reform (31). The potential spheres of conflict include (37):

- responsibility – the model of clinical profession lays emphasis upon an individual, the model of total quality management stresses the process;

- managing – the model of clinical profession denotes the management of activities for the protection of patients by professionals, while the model of total quality management refers these to the management, with doctors to be included in the process of managerial decision-making to fully solve the problem of quality, while the initiative lays upon the management; and
- autonomy and responsibility – the model of clinical profession implies full autonomy and responsibility of a physician for his or her work, and the model of total quality management means that the responsibility of the doctor lays both for the process and for the outcome of care, but with due regards to financial limitations.

Despite the stated limitations, adoption of the model of total quality management is a challenge to all professionals to mind the quality, to evaluate and regulate their work, and to protect their professional autonomy. Doctors easily adopt this model in case necessary data are provided by the management, and when it is required from the doctors to concentrate onto clinical activities.

Implementation of the change management philosophy in the process of introducing the new health policy at all levels is indispensable, as some resistance and opposition is expected from all those to be affected the most by the change (doctors and managers in certain health institutions), without whose compliance and participation there can be no essential change. The management of change is a process which ensures efficient functioning of an institution under the conditions of the change being introduced (38). The efficient change management requires thorough planning, complete communication, persuasion of the employees in the validity and usefulness of the proposed change, involvement of the employees into those processes whenever possible, and following the execution of the change. The crucial factors for the success of the change are:

- motivation – existence of key reasons to change the present unsatisfactory situation,
- vision – clear and practical image of the desired future state of affairs, and
- next moves – comprehension of all successive steps necessary for the progress toward reaching the vision.

All three factors are indispensable and it is necessary to make them mutually multiply in order to effect the change:

change = motivation x vision x next moves

In any management of the change as a group process special attention has to be taken in regards to the resistance of all the actors involved in the change, which is manifested as denial of the need for a change in the first place, or as passive opposition revealed in absence from the necessary activities or as active resistance, with specific engagement in blocking the introduction of a change (39). Therefore, it is critical that the priorities be set as clearly as possible, and they have to be presented to everyone. It must be taken into consideration that all early reactions, whether positive or negative, are a good sign. The principal way of involving the employees is: to secure information (reasons for the change, where the change leads to, how to achieve the change – the role of the employees), one's own planning of the activities, and demonstration of empathy and support by the managers. The key activities for an efficient change management are shown in Table 2.

Table 2. The key activities for the efficient change management

INVOLVEMENT OF EMPLOYEES	ASSURANCE OF INVOLVEMENT
• couple the change with the employees' needs • approve one's own planning • prepare the employees for the assigned duties • prepare the employees to manage stress • accept »resistance« as sign of personal struggle, not opposition to change • celebrate the progress	• establish a clear vision for the envisioned future state of affairs • assure that managers be the role models • regulate the system of recognition and awards • make the process of change a team effort • secure a current, open, two-way flow of information
STRATEGY OF SUPPORT TO CHANGE	PROJECT MANAGEMENT
• build partnership involving key persons • maintain support of the gained sponsors • strive for a small initial success • focus effort where it is most effective • reinforce changes neutralizing hidden opponents	• share out responsibility for the process • develop a plan which includes both human and technical resources • establish structures for process management and backing • establish reliable system of measurement, following, feedback information, benchmarking and learning

Source: Hutton D., Managing Purposeful Change (cited 2004, March 23). Available from URL: http://www.dhutton.com/change/change.html

Bearing in mind that in the case of the reform of the health care system there will be individual instances of cutting down of certain capacities, special prudence is advantageous in this particular case, the one termed »reduction« in literature (34,40). The basic activities in reduction are the following (40):

- reduction of personnel (dismissals, withdrawals, transfers);
- organizational restructuring (elimination);
- reduction of technical capacities (number of beds, operating theatres, sale of equipment);
- change of purpose (in hospital room into an outpatient office of physician).

The problems ensuing reduction are the loss of credibility of the managers, heightened »politicking« and rivalry among managers at different levels for the positions in the reduced organization, lowered motivation, and increase in voluntary discharges. Possible solutions for this kind of situations are elimination of ambiguity that the reduction creates among the employees and an increase of communication between the managers and the staffs.

Education of managers for the new health policy

The reform of the health system, particularly through decentralization and flexibility of the management, greater autonomy for providers of health care services, and introduction of active privatization, emphasizes the need for educated managers who will possess far more sophisticated skills than it was the case in managing the hierarchical administrative systems in the past (14).

Delegating the responsibility for the recognition of the needs for health among specific populations and their satisfying at lower referential levels also requires from the managers to be educated in public health, including epidemiology. They should be acquainted with the methodology of assessing the health status, in programming for health, and in the techniques of monitoring and evaluation. The health managers now have to possess skills both in strategic management and in managing individual institutions. At the same time it is estimated that all other health professionals must be educated in faculties of managing people, negotiating, and communicating (14).

Expansion of the managerial capacity requires not only the initial action, but also the medium and long-term educational programmes (28):

- Initial and prompt education of the managers means enabling them to manage institutions in a complex period of transition (especially the top managers in an institution). Short courses are to ensure mastering the skills in the following fields: concepts of management, strategic and operational management, financial management and accounting, information management, management of interpersonal relations and conflicts, and management of change.

- The medium-term educational project is to provide for programmes of continuing education for all the existing and potential managers in the health system.
- The long-term project is required to establish formal programmes of education, which would stimulate the concept of professionalism and high quality management, in the framework of postgraduate master's studies in health care management at the university level.

There exists a special need for the stimulated development of managerial activities based upon the working place of a manager, not the classroom.

The educational needs can use rich experience of the European Health Management Association – EHMA, which already offered similar services to the European countries in transition. Recommendations of this Association refer primarily to the development of education for the management in health care as management of all resources in public funds which are directed to the improvement of population health (41). Skills acquired as part of this education are related to the creation and management of the change which leads to the population health improvement, the skill of talking with and listening to a health care consumers, development of the information system which instigates the public health by integrating epidemiological data and those from sociological research, application of marketing, development of the organizational forms, and project management. In order to achieve full efficiency, the managers in public health should possess special technical skills and general managerial mastery. Challenges imposed by the new health care require such an approach to the education of managers which accentuates dynamic dimensions of a »learning organization« and the management of change (42). The management principles stemming from the conventional bureaucracy in the health care system are neither relevant anymore nor are they suitable – in case they ever were.

Today increasing attention is focusing on the evidence based health policy and the benchmarks approach as a new tool for policy analysis (18,43). The interfaces are made between researchers and the users of research – policy makers in order to improve the health policies worldwide. „The permeability of the interfaces becomes important given the potential problems in the transmission of views and findings between researchers and policy-makers. Issues around interfaces need to be considered at various stages including priority setting, commissioning of research and communication of findings" (18). The benchmarks approach focused heavily on the needs in reforming a technologically advanced but inefficient and inequitable system that lacked universal coverage and needs health policy changes (44,45).

EXERCISE: Health Policy

Task 1: Comparing health policies

Students should work individually (or in a country-based groups), in order to compare indicators of Health Policy in their own country and at least two countries – one from region and developed one. To fulfill this task, students should use the site http://www.observatory.dk, where are available all relevant information regarding to current Health Systems. They should try to use different health policy indicators listed in the WHO list and to use examples from good articles relate to health policy, which can be found at the internet publication of some journals (British Medical Journal, Health Research Policy and Systems, Bulletin of the World Health Organization).

Oral presentation or seminar paper should be delivered upon this individual work.

Task 2: What is Your Policy Objective in Health Policy Cycle?

Students should work individually to highlight an issue or problem that the government is currently ignoring (*agenda setting*). Then they should propose potential policy responses to a given issue (*policy formulation*). In the next step they would try to influence the selection of a potential policy response (*policy legitimating*), improve the implementation of a law / policy / programme (*implementation*), evaluate a law / policy / programme (*evaluation*) and, eventually, try to describe the change / terminate an existing policy (*policy termination or change*). The time necessary for individual work is 60 minutes, after that students prepare posters of their policy cycles (time available: 30 minutes) and later some of students present the results of individual work – 30 minutes. Total time necessary for this task is 120 minutes.

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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT **A Handbook for Teachers, Researchers and Health Professionals**	
Title	**Public Health Framework in the European Union**
Module: 3.2	**ECTS (suggested): 0.25**
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Keywords	Public Health, European Union, history, legal basis, policy development, Open Method of Coordination (OMC)
Learning objectives	Applying the content of this module the students will be able: • to differentiate the dimensions of national and European public health policy; • to identify key areas of EU's involvement to complement national policies in the field of public health; and • to put the own professional field in relation to European fields of action.
Abstract	European activity in the field of public health started late, and the diversity of public health systems makes the development of common strategies more difficult than in other fields. The legal basis of EU's action in the field of health is fairly basic and simple but implies a broad and strong impact not only for health related matters but also for other political fields. EU's activity in the field of health is based on a public health point of view. Since its start in special fields it has grown into whole programs but constantly limited by member states' responsibility to organise public health systems. Besides this factual limits the role of the EU in and the implementation of its public health policy is debated by people and experts. Still, the importance is growing and new strategies to develop public health policies such as the Open Method of Coordination are implemented which becomes even more important in the light of the enlargement of the European Union.
Teaching methods	Lecture, individual work, group work
Specific recommendations for teacher	This module should be organized within 0.25 ECTS, out of which one third will be under the supervision of teacher, and the rest is individual students work. After an introductory lecture the student should become familiar with information sources of the European Commission at the internet or by ordering through common mail. By looking for related EU legislation the students would become aware of the relevance for her/his field of profession (individual work). Results can be presented and discussed in groups.
Assessment of students	Presentation or essay discussing the national or professional impact of one particular field of EU's Public Health Policy.

PUBLIC HEALTH FRAMEWORK IN THE EUROPEAN UNION

Thomas Hofmann

In history, public health has been reinforced at those points when individual health care and cure of health problems were failing. The classical examples are all the epidemics in the past centuries. New problems such as AIDS or re-emerging of tuberculosis were again a point in time for more action in the field of public health. Further, modern behavioural and social patterns and similar problems in European Union countries needed an international approach since most problems did not stop at the border (1). The European Union, primarily concerned with economic matters, had to develop a new basis for that kind of action. On the other hand, new structures had to be developed since the traditional "health care services in and of themselves do relatively little to bring about an improvement in the health status of populations" (2) and the European Union was faced with a variety of health systems in the course of enlargement (3). Moreover, traditional health services even hinder progress in public health. The dominance of treatment in the reimbursement schemes of established health care systems, the powerful role of health professions in many countries and economic restrictions kept the mostly state-dependant public health efforts off political agendas (4).

Public health as „the science and art of preventing disease, prolonging life and promoting health through organised efforts of society" covers more fields than just economics, the original starting point of the European Community (5). The Treaty of Rome did not provide any legal basis for public health activities (3). An awareness of inadequate results achieved by the established public health systems, possibly supported by a general changes and openness for new strategies to improve the health of the people (6), allowed new health threats to be dealt with. The first so-called "action plans" started in 1987 on the basis of the Single European Act. Action was taken to prevent cancer, AIDS and drug consumption and trafficking. Still, there was no basis for European legislation in the health sector. Only in 1993, the Treaty on European Union (TEU - the Maastricht Treaty) created the first legal competence for the Community. Article 129 foresees the coordination of health programmes and policies of the Member States, a significant focus on prevention of diseases, the obligation to combat major health problems (e.g. drug dependence) and the

Community's co-operation with other organisations. Based on that article, the Commission sets out indicators to determine priorities for action (7):

- a disease's impact on mortality and morbidity;
- a disease's socio-economic impact;
- how far a disease is amenable to effective preventive action; and of particular importance,
- how far there is scope for Community action to complement and add value to what is being done by the Member States.

The current legal basis for Public Health

The Treaty of Amsterdam changed the wording of Article 129 and was renumbered Article 152 of the EC Treaty (see Box 1).

Box 1. Article 152 (ex Article 129)

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States' action in reducing drugs related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Apparently, as in any other national legislation there are several more articles touching the field of public health. Currently, the legal framework for health in the European Union is provided by the EC Treaties and Case law from the European Court of Justice. Besides Article 152 EC, the next could also applied:

- Article 3 EC (The activities of the Communirty shall inlude… „*a contibution to the attainment of a high level of health protection*");
- Article 95 (3) EC Internal Market („The Commission, in its proposals… concerning health, safety, environmental protection and consumer protection, *will take as a base a high level of protection,* taking account in particular of any new development based on scientific facts");
- Article 174 (Health and Envronment: „Community policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment, protecting human health,…")
- Article 30 EC (Allows member states to prohibit the marketing of products from other EU countries to protect public health but only where there is scientific evidence in support, and as long as it is not a disguised restriction on trade).

Other legislative areas where health is mentioned are: Article 39 and 46 (free movement of workers), Article 137 (workers' health and safety) and Article 153 (consumer policy). However, there are also key areas where health is not mentioned: the Common Agricultural Policy (CAP) and Common Transport Policy. Nevertheless, Article 152 keeps the most central role by targeting the health improvement, disease prevention, anticipation of sources of danger to health and ensuring that all EC policies protect health.

The Community's public health policy is still seen as subsidiary to the Member States' effort, but compared with other Community policies, public health has been accorded greater weight. Through certain non-binding resolutions in previous years, reports prepared by the Commission, particular action programmes and funding of research work, the Community has now been able to implement a genuine public health strategy (details are available from URL: http://www.europa.eu.int).

According to the treaty, the protection of human health is now to be ensured in all Community policies and activities, both in their definition and in their implementation. Until recently it had only to be a constituent part of Community policies. The meaning of the new article also goes beyond the prevention of illness and disease to include the improvement of public health and the obviation of sources of danger to human health. It is important to note that Article 152 establishes a link between public health policy and the donation and use of human organs and substances of human origin, as well as between public health policy and veterinary and phytosanitary fields (7). This reflects the awareness of the importance of a common and consistent European public health policy in view of the BSE crisis ("Mad Cow" disease). In the famous Medina Report on the BSE crisis to European Parliament, 1997, it was stated: "The EU should have a clear legal base enabling it to exercise its powers in the field of public health. It should be made impossible for the subsidiarity principle to be used as means for Member States to oppose the development and application of measures… necessary to protect public health". At several points though, the Article 152 emphasises the Member States' responsibility for organising the delivery of health care, including action in the public health field. That seems to be the obvious limit for European public health policy.

As the Communication from the Commission to the Council on the development of public health policy in the European Community (8) shows, there is a clear intention to act at a subsidiary level by supporting national and European legislation with tools for decision making. Health monitoring, surveillance and tackling health determinants are lacking in almost all European Union countries. The exchange of experience and the collation of epidemiological data should help to prevent or reduce the number of premature deaths by introducing a public health aspect into other Community policies, and to cope with the enlargement of the European Union (7).

Part of the above mentioned Communication is a public health framework which includes the so-called action plans of the Commission in the field of public health, since 1993. Previous public health programmes were oriented towards cancer, AIDS and other communicable diseases, drug abuse, pollu-

tion related diseases, health monitoring and health promotion. Up until 2000, eight programmes were set up. These action plans have now been extended to one global action plan until 2008 – Public Health Programme (2003-2008). Priority objectives of New Public Health Programme (2003-2008) are the following (http://www.europa.eu.int):

1. to improve information and knowledge for the development of public health;
2. to enhance the capability of responding rapidly and in coordination fashion to threats to health; and
3. to promote health and prevent disease through addressing health determinants across all policies and activities.

The components of the new public health strategy of EU are a new public health framework and a coherent approach to health across Community policies and actions. The first strand (*Improving health information*) is related to health monitoring, mechanisms for analysis and reporting and information to authorities, professionals and the public. The second strand (*Responding rapidly to health threats*) includes: work on communicable diseases (building on the network) and rare diseases, anti-microbial resistance, blood safety and quality, organs and substances of human origins, non-communicable disease threats, and actions on physical agents. The third strand (*addressing health determinants*) comprises: strategies and measures on lifestyle-related determinants (tobacco, alcohol, drug dependence, nutrition, physical activity, sexual behaviour, mental health), strategies and measures on socio-economic determinants (benchmarking on health inequalities, health insurance and health service arrangements, access across borders), and strategies and measures related to the environment.

Development and implementation of European Union Public Health policy

The Commission's public health department (Directorate G), which is split into four units, is integrated into the Directorate General for Health and Consumer Protection. At the present stage, the expenses for public health are cut down, which results in a shortage of staff in the Commission services (9). Fruitful and successful work in the public health field was carried out immediately after the new legal basis for it was introduced in the Treaty of Maastricht as Birt et al. (1997) describe. In 1993, the Commission set up a working group consisting of nearly 70 experts taken from almost all the Member States. The task was defined as being to submit proposals for policy development in cer-

tain priority areas. In the final report the expert group describes its recommendations for the short, medium and longer term in the areas of health data and information, accidents and injuries, pollution-related diseases, rare diseases and consultation mechanisms for public health, each area being split into preventive action, health data, consultation mechanisms and training and research. The expert group took into account the assessment of health needs, intervention based on evidence, as well as socially acceptable and politically credible policy development, which was based on democratic principles. In self-evaluation, the expert group rates its work as effective and efficient, but „time consuming and exceedingly expensive"(10). Looking at the policies pursued by the Commission since then this self-appraisal seems to be realistic, and the fact that the Commission is still working with several expert groups in many areas confirms the advantages of that kind of policy development. Regarding the discussion about national implementation of European Union legislation it also seems to be the only way to ensure the compliance of the Member States, as the nations are represented in those groups.

For many years the European Union has co-operated with the WHO and more particularly with the Regional Office for Europe. In recent years the Member States' mandate to the Commission in WHO negotiations has become stronger. For the first time, the Commission has been representing all European Union countries in the negotiations on the WHO framework convention on tobacco control. In other areas, inter-organisational frameworks in the public health field are being developed, and there is cooperation, particularly with regard to Central and Eastern European countries (6).

At some occasions the development of a European public health policy is pushed forward by decisions of the European Court of Justice. A very famous example has been the Kohll/Decker file on cross-border treatment in 1998. This process is known as „Negative Integration" since it shifts competence to the EU without the Member States positive agreement. In recent years the so-called Open Method of Co-ordination (OMC) as a working method becomes increasingly important. This process is known as part of „Positive Integration" since Member States are actively involved in policy making. Originally developed in the field of EU's social policy since 1997 it has been introduced in the field of health after the Lisbon Summit 23 and 24 March 2000 to allow certain work to take place in areas where competence was not clear between the Community and the Member States. This method is clearly based on the principles of subsidiarity and decentralisation. Especially in the light of the enlargement of the European Union it seems likely to become a very important tool of policy-making as it creates soft law. Soft laws are recommendations

and unsolicited agreements between several partners which are formally non-binding but create an international and diplomatic pressure to be applied.

The procedure is similar to any benchmarking process. The Council decides measures which should be reflected in national policy. The Member States present their efforts in reports to the Council and the Commission. The Council formulates recommendations to be taken into account by the Member States and so on. The first results of this working method are in the beginning to be evaluated (11).

The view of people and experts regarding European Public Health policy

Bearing in mind the political debates in almost all countries in the field of health care, it seems self-evident that any European policy in that field needs to respect the sensitive areas in each country. As discussed above the Treaty clearly mentions the organisation of health care systems as the responsibility of Member States. However, interference is of course inevitable. As a representative survey among actors in the health field shows, the acceptance of such interference varies greatly between the European Union Member States (12). It seems that in some countries no widening of European Union competence in the health care field is wanted by the people. The only fields where European Union action is regarded as reasonable are health promotion, medical ethics, quality assurance and standardisation of education levels for health professionals (13).

More concrete expectations from a European health policy can be noticed, when looking at recommendations developed by high-level experts. Still, health care systems remain untouched. The main demands are for a stronger monitoring system, more research activity, fewer overlapping activities of Member States, the European Union and other international organisations in the health care field, and greater availability of shared knowledge, information and experience. In particular, evaluation and health technology assessment should play a more important role. To provide the European Union with more continuity the six monthly Presidential cycle should be replaced by long term health strategies related to those developed by international health organisations (14).

Not only content but also delivery of political strategies is seen controversial. Whereas Robinson/Graham (15) note the lack of personnel in the Commission to deal with the requirements, the European Health Care Management Association (EHMA) is very sceptical regarding a growing Commission and prefers the Commission to play a more supportive role.

Public health experts see further inconsistencies in European Union's health policy (14). As Article 152 outlines, public health approaches should involve all policies. One reason for that could certainly be the lack of evaluation of EU's public health programmes not having a significant impact in other political fields.

The policies

A major issue for the European public health policy arises in relation to the enlargement of the Union. As Bojar the former Minister of Health of the Czech Republic points out, there is a great need for a reduction in the differences in the quality and availability of health care in the whole of Europe (1). This means that certain standards for health care systems have to be established in order to standardise. Fischer, the former German Minister of Health, notes the same fact and points towards the necessary harmonisation of health care systems and social standards up to a certain point (16). But „there cannot be and will not be a European standardisation or even harmonisation of the national differences, because of the peculiarities of the traditionally evolved structures specific to each individual Member State" (16). The similar wording clearly shows that the limits for harmonisation and standardisation are not absolutely set and the individual interpretation by each politician will lead to permanent discussions on that key topic of health policy.

Besides that political hot potato, policies do seem to coincide quite closely with scientific expert opinion. The summary of a meeting with European health officials presented by Fischer repeats the recommendations as described above. In addition, the financial situation of health care systems is given greater attention since it seems obvious that a higher expenditure for health care does not necessarily lead to a higher life-expectancy of populations.

EXERCISE: Public Health in the European Union

Task 1: Students should use recommended readings in order to become familiar with information sources of the European Commission in the internet or by ordering through common mail. By looking for related EU legislation the student can become aware of the relevance for her/his field of profession (practical work). Results can be presented and discussed in groups.

Task 2: Students are asked to write an essay, discussing the national or professional impact of one particular field of EU's Public Health Policy. Essays will be assessed and presented in group.

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Recommended readings

- European Union web-based guide to Union Policies at http://europa.eu.int
- Holland WW, et al, ed. Public health policies in the European Union. New York-Oxford-Tokyo: Oxford University Press 1999.
- Normand CEM, Vaughan P. Europe without frontiers. Chichester-New York-Brisbane-Toronto-Singapore: Health Press 1993.
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HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Targets for Health Development**
Module: 3.3	**ECTS (suggested): 0.50**
Authors, degrees, institutions	Dr. Rudolf Welteke, State Institute of Public Health of Northrhine-Westphalia (LOEGD), Bielefeld, Germany
Address for Correspondence	Dr. Rudolf Welteke State Institute of Public Health of Northrhine-Westphalia (LOEGD) Westerfeldstr. 35/37 D-33611 Bielefeld Germany E-mail: rudolf.welteke@loegd.nrw.de
Keywords	Health targets, health policy, health strategy, health indicators
Learning objectives	At the end of this topic, the students should be familiar with: • principles of target setting; • examples of world-wide health strategies and targeting settings; • process of developing and implementing a target programme.
Abstract	Health policy requires a clear outfit and a number of comprehensive and visible goals in order to become accepted within the population and the specific target groups. Identification and monitoring of health targets in programmes introduce more transparency and more visible success into health policy. This paper presents highlights and the background experiences, which have been accompanying the development of health target programmes within the last three decades. Moreover, you will find some aspects of developing and implementing a target programme and diagnostic tools in order to find out, if the introduction of health targets could be an appropriate tool for problem solving in a specific political environment.
Teaching methods	After an introduction lecture students will work in a small groups on identification of health targets (based on health monitoring data) and compare international, national and their own health targets. Work will be followed by group reports and overall discussion.
Specific recommendations for teacher	It is recommended that the module should be organized within 0.50 ECTS credit, out of which 0.25 of ECTS credit will be done under supervision (lecture and group discussion), while the rest is individual student's work. It is supposed the 1 ECTS is equal to 30 hours. Teacher should advise students to use as much as possible electronic management libraries during individual work.
Assessment of students	Multiple choice questionnaire and written report.

TARGETS FOR HEALTH DEVELOPMENT

Rudolf Welteke

Introduction

The idea to build up instruments in order to introduce more transparency and more visible success into health policy is a simple but difficult option at the same moment: the simple aspect is that health policy requires a clear outline and a number of comprehensive and visible goals in order to become accepted within the population and the specific target groups. The more difficult aspects are associated with the management process that is needed to make target programmes successful and efficient; this process has to give answers to questions like: What kind of target development should be instigated? Who are the suitable persons and institutions that should get involved? What is the appropriate role and mixture of policy makers, practioners, and technical experts within the process of development and implementation of health targets?

The history of health target projects is a story with ups and downs which has had to find its path between these two areas: the simplifying area on the one hand and the area of scientific approaches on the other hand. The task of the following chapters will be to give a short introduction into the highlights and the background experiences which have been accompanying the development of health target programmes over the last three decades. Moreover you will find some diagnostic tools in order to find out, if the introduction of health targets could be an appropriate tool for problem solving in a specific political environment.

Some Principles

The roots of target programmes can be found in the sector of economics and project management: if you are planning to create and launch a specific product in a defined section of the market, you have to make sure that a series of consecutive elements exists:

I First you have to decide, what *kind of product* you are going to develop – this is the first step of target setting. This step is associated with the creation of a clear outline of the product with a well defined idea what you are going to offer.

II The second step of development is developing the process goals which effect the way in which the product should be introduced into the market: *Which effects and gains should be achieved by the introduction of this product?* This type of question is including at least two effects, which can be described in terms of target setting:

Target A: the aimed effects in the target group (e.g. the grade of distribution of the product X in the target group Y);

Target B: the aimed effects according to the producing and/or selling company (e.g. number of produced elements; amount of financial advantage)...

III As the target setting process is a part of an entire planning process the combination with a time schedule is a must. *Matching the milestones of this schedule* is another (the third) important element of the target setting process.

IV A fourth target aspect is associated with the task of *meeting certain pre-defined standards of quality* of the product. This element leads into the area of quality assurance. If you are the only producer of this type of product you are dealing with your own standards of quality. If there are more comparable offers your product will be subject to a benchmarking process.

There are a lot of more detailed aspects which are linked with the process of target setting. For example the question how to quantify the achieved effects is an important one, if you are going to set targets in the health policy sector. As you have to deal with a lot of effects in the health area, which produce some difficulties if you try to meet high standards of quantification, you have to find a smooth way in order to create a set of appropriate indicators linked with those targets and strategies you want to introduce. On the one hand, quantified targets appear to be the type of "better targets". On the other hand you usually have to minimise the amount of resources if you want to be successful in implementing an entire health target programme – so you will have to be careful with the definition of high level standards if you are going to develop and introduce appropriate *evaluation* procedures.

Figure 1. Some relevant elements of the target setting procedure

stage	keyword	task
I	definition of a product	investigation of the market, designing
II	introduction of the product	advertising, product placement
III	time schedule/milestones	schedule the project, element ranking
IV	quality of process & results	development of indicators, evaluation

History

The "Health for all" programme of WHO's European Regional Office

The history of health targets is a story of development which took place in different core areas. From the European point of view there was a first relevant attempt to develop health targets in the Nordic (Scandinavian) countries - especially Finland - in association with the European regional office of the World Health Organization (WHO) in Copenhagen/Denmark. This preliminary was carried out in the Seventies and was confirmed in the general outline of the strategy "Health for all" by the regional assembly of the European nations in 1977. A major campaign was carried out when the WHO publication „Health for all 2000 - ..." appeared in 1985 and was distributed in different languages with a large number of copies. The programme included a comprehensive health target approach which was based on 38 elaborate health targets (1).

These 38 targets focused on relevant topics of health policy in western, industrialised countries. There was nearly no similarity with the „Ten global health targets" which had been released by the WHO headquarters of Geneva some years before and had been adjusted in the late 1990s (2). The 1985 European regional health targets, which were revised in 1991 (3), have always been associated with a serious attempt to lay more stress on the social equity issues of health and health care – especially by giving target number one the headline „More equity in health affairs". This was an indisputable demand for more social justice within the European societies and health systems. This WHO target programme included the option for a positive social change in European countries but also contained the substrate for a lot of political controversy in the different European nations and regions. On the one hand the „Health for all" strategy led in a convincing way to several interesting and sophisticated national and regional health target programmes, designed and carried out by „early adopters". On the other hand the programme produced a lot of non-adopters, especially among more conservative health politicians, who for example did not accept the message of more equity or at least did not believe in alterations of social structure of that big size the WHO programme suggested.

Actually the entire political impact of the WHO target programme can only be understood in depth by reflecting on the policy differences between the socialistic and capitalistic states of the Seventies and Eighties of the last century. Basically the *Health for all* approach has been a comprehensive health promotion programme with a new, broader understanding and definition of

healthy conditions. Especially the socialistic states had been working hard in order to introduce the reflection of the *healthy conditions approach* into the programme. This approach was going to balance the former *health education* approach, which has been favoured by the western governments up to the late Seventies, and which prioritised the individual health behaviour.

The historical point of view creates the opportunity to ask, if WHO's target inititiative would have been more successful, if it would have come with less demands about social alteration and political change. There is the suggestion that the consensus level to adopt a target programme like this at national, regional or local level would have been better, if the political power of the WHO programme would have been more discrete – but: probably there would have been other obstacles arising in this virtual case – e.g. the level of perception of the programme might have been deminished to a critical degree. Anyway – there are some experiences with WHO-designed health target programmes, which are worthwhile to be mentioned (below).

Health21 – the renewed health target strategy of the WHO for the new century

In the late 1990s the WHO published a renewed version of the "Health for all" approach, called *Health21*. The first remarkable change of the new programme was the reduction of the number of targets from 38 to 21. The reduced new WHO strategy was an answer to some critical remarks which stated that the former 38-target approach did not meet the requirements for a consistent and convenient programm design.

Another important change was introduced by the political re-mapping of Eastern Europe which took place in the 1990ies especially after the decline of the Soviet Union. The WHO had been facing a new and strong imbalance between eastern and western countries in the European region. On the other hand the renewed 1998 approach of the WHO was a change to a more economically driven policy and a change to a system of health policy based on health determinants. It has been an adaption to a radically changed economic and political situation in the European region (4,5).

Target programmes of members of the Healthy Region Network

Especially the WHO-associated *Healthy Region Network* has been producing some important approaches. There was a working group meeting in 1992, which led into a presentation „on the development of subnational policies for health" (6). In addition, there had been an International Workshop

on Target Setting in Brussels in 1996 with contibutions of those network members dealing with target programmes: Wales (Great Britain), Catalonia (Spain), Oestergoetland (Sweden), North Rhine-Westphalia (Germany) (7).

An elaborate health target programme has for example been developed and implemented in ***Wales.*** Wales is situated in the south-west of Great Britain with a population of about 3 million. The Wales target programme was announced in 1989 by the Welsh Office as an initiative: with the Strategic Intent and Direction, which aimed to "take the people of Wales into the 21st century with a level of health on course to compare with the best in Europe". The initiative covered 10 areas where health could be improved. These areas accounted for about 80 per cent of the health expenditure in Wales. Intervention in each of these areas had been planned by three main principles: *(i) Health Gain:* focusing on improving health by, e.g. shifting resources to more effective treatments; *(ii) Making services more responsive to people's needs and preferences:* e.g. considering the total effects of services on people's lifes rather than narrower clinical perspectives; *(iii) Effective Use of Resources:* e.g. providing an appropriate balance between prevention and promotion; diagnosis and assessment; treatment and care; and rehabilitation and monitoring (8,9,10). An evaluation of the Welsh programme was published as an official „Report by the Comptroller and Auditor General" in 1995 (11). The programme has been renewed after the British change of government in 1998 and was published as a (bilingual) consultation paper titled „Better Health. Better Wales" (12). A strong focus of the new approach lies on health inequalities. It includes some interesting additional remarks on „investing in the future" e.g. by mentioning strategies based on advanced health impact assessment procedures (13). The policy paper was followed by the publication of a strategic framework (14). An evaluation programme is continuously carried out – results are e.g. available via internet (15).

Catalonia – the 6-million-people region in north-eastern Spain with its capital *Barcelona* has been developing a health target programme which surprises by an exorbitant great number of single targets (about 600). The Catalonian approach is an elaborate, high-level target programme which was published first as a framework document in 1991 (16). The first *Health plan for Catalonia* was published in 1993 (17) followed by a series of further updates and publications (18,19,20,21,22). The Catalonian target programme is related to a thoroughly planned and realised health monitoring and reporting system. Due to this special situation it had been possible to quantify each of the single targets. A critical assessment of the Catalonian approach may produce the result that it is overdetailed and at last it might be difficult to find out - in the

mass of findings - what really had been the (political) success of the entire programme. Anyway – the Catalonian example is an excellent and impressing model for studies. Especially the broad range of positive opportunities, which lies in a tight linkage between health monitoring and a subsequent target programme are visible in the Catalonian model.

Another early regional approach has been worked out in the southern part of Sweden, in a region called ***Oestergoetland*** (population: 400,000; capital: Linkoeping). The Oestergoetland 1988 Health Policy Programme set five overall goals: *(i) Oestergoetland County Council – a Health County Council; (ii) Health promotion and disease prevention* – that is equally accessible to all the people of Oestergoetland; *(iii) Health promotion and disease prevention of high quality; (iv) Health activities that satisfy the needs of the population; (v) Community participation in health activities*. The 1990 strategy for implementation focused on six areas of intervention: healthy lifestyles; accident prevention; musculosceletal disorders; health of children and youth; health of young parents; health of elderly. 26 quantified targets were defined by a 50-person expert and layman board. The positive example of this regional approach is highlighted by an ambitious organisational process combining a lot of health and social policy challenges and including in particular the opinion of NGO's which are active in the region (23,24,25,26).

Healthy Region Network founding member ***North Rhine-Westphalia***, a 17-million-population state in the western part of Germany, has been starting its own health targets programme „*Ten priority health targets for North Rhine-Westphalia*" in 1995 (27). The ten targets are:

1. Reducing cardiovascular disease
2. Controlling cancer
3. Settings for health promotion
4. Tobacco, alcohol and psychoactive drugs
5. Environmental health management
6. Primary health care
7. Hospital care
8. Community services to meet special needs
9. Health research and development
10. Health information support.

The North Rhine-Westphalian approach has been starting as an evocative political programme – after the WHO's *Health for all* programme has been treated in Western Germany for more than one decade in a more reserved way. The reduction to a number of 10 targets (derived from the 1985 WHO 38

target programme) was a reasonable political decision in order to adapt the size of the target programme to the limited resources of the North Rhine-Westphalian health policy sector. Up to the year 2000, which has been marking the halfway point of the declared first decade of NRW's target programme implementation, there had been two (of ten) target implementation programmes released: target 4 "Tobacco, alcohol and psychoactive drugs" and target 2 „Controlling Cancer" have been described by elaborate implementation brochures and set into action by expert teams. In addition to the both implementation schemes mentioned above an evaluation approach was developed and published in order to assess the realised parts of the target scheme.

There has been an official declaration of all important institutions of the health care and prevention sector in North Rhine-Westphalia in 1995 to get involved in the programme in an active way. The scheme of this target programme and some of it's technical patterns have become parts of the German national target approach, which begun in 1999 (see below: *national approaches*). A short documentation of the North Rhine-Westphalian target approach (28) is also available in English (29). There is a series of publications available in German language (30,31,32,33).

Selection of national approaches

The **British** health target programme ***"Health of the Nation"*** has been focusing on more medical aspects of the broad range of public health topics. Actually there was a serious approach to establish a national health target programme, which was backed and released by the national government and the parliament in 1992 (34,35,36,37).

In particular the aspect of social equity in health affairs was disguised under the conservative period of Mrs. Thatcher's government in terms like "social variations". This development was stopped when Labour Party won the 1998 elections – but: the *Health of the Nation* target programme was assessed immediately after the political change (38) and cut down drastically – although there was a nice new label created: ***"Our Better Health"*** (39). In order to bring the programme closer to the people's reality the renewed strategy is said to be more "focused and disciplined": *"But operating on too broad a front risks dissipating our energies on too many goals – and achieving none. The strategy must be focused and disciplined*". That is why the Government has identified four priority areas:

1. heart disease and stroke
2. accidents
3. cancer
4. mental health (39)

The British target programme is worthwhile being studied thoroughly: it is a long term project which has had some important impact on the British health policy. This importance was underlined by the continuing of this policy concept even after the historical 1998 policy change. The relevance of the British health target model is based on an excellent technical advice by several expert teams. The output of these teams – which have been partly run by the government itself, partly embedded in the staff of several cooperating universities – means especially a high quality support for the continuous statistical analysis of the programme outcomes and the consecutive strategical and technical steps of adjustment.

The redesigned British approach tries to get solutions in two key areas:

1. "to improve the health of the population as a whole by increasing the length of people's lifes and the number of years people spend free from illnesses";
2. "to improve the health of the worst off in society and to narrow the health gap" (39).

So the new programme is setting high standards according to the political framework, especially in the efforts of narrowing the health gap and of tackling the health related symptoms of social inequalities. While reading the renewed strategy of 1998 and these highly ambitious target modifications in the field of social policy there is the impression arising that there is a lot of political declaration. It is obvious that this type of target setting – and especially the very enthusiastic effort to bring in the topic of combating the social inequalities, ("Black Report" – and consequent publications: 40,41,42,43,44) – have been inducing a lot of political discussion and producing a reasonable series of scientific investigations on this topic. On the other hand these targets don't have the touch of "realistic targets" in a narrower sense: there are too many implications, such as addressing the current baselines of social structure and economic principles of the entire (British) political system, which probably will not change based on the demand of health policy intervention – even if the programme is declaring "we are in this for the long haul..." (39). Especially it will be of some interest to observe the long term outcome of this target initiative under the auspices of the outspreading *New Economy*.

The ***Australian target programme*** (45,46) is one of the elaborate positive examples within the worldwide health target community. It has been tailored as a modification of the WHO target approach. The framework was developed in 1993 and included a range of goals and targets grouped in the following four areas:

1. preventable mortality and morbidity
2. healthy lifestyles and risk factors
3. healthy literacy and health skills
4. healthy environments

Comparable to the British approach there are concrete actions focused on cardiovascular disease, cancer, injuries and mental health, as these fields are the four national priority areas of the health ministers. The Australian programme is includes quantified targets, e.g. Lung Cancer.

Lung cancer is the most common primary cancer in Australian males and the third commonest in females. Targets included:

- to reduce mortality from lung cancer amongst males (by 12 percent by the year 2010 from a baseline in 1990 of 58.4 deaths per 100,000); and
- to reduce mortality from lung cancer amongst all females (by 8 percent by the year 2010 from a baseline in 1990 of 16.8 deaths per 100,000).

Proposed targets included:

- to reduce mortality from lung cancer amongst Aborigines and Torres Strait Islanders and all people from low socioeconomic groups (46).

The ***Healthy people 2000*** target programme of the **United States of America** represents one of the most impressive documents of the health target literature: the initiative was prepared in the 1980ties (47,48), unveiled in 1990 and the strategy was published in 1991 (49). The 1992 edition came along with three additional big size volumes: *(i) Consortium Action; (ii) Public Health Service Action; (iii) State Action* (50,51,52). These publications reflect a cooperative approach, which is the organisational backbone of the entire programme. On the other hand they produce the broad range of approx. 330 objectives and more than 600 single measures, which are related to 22 areas of activity. These *year 2000 targets* had been related to baseline data from the 1980ies annual NCHS health reports. The sophisticated approach is

characterised by a highly detailed differentiation of target groups (white, black, hispanic, American Indian/Alaska Native, low-income people etc.) and by a high grade of quantified descriptions of health settings and trends. The 1992 edition was continued by a series of annual evaluation reports (53, 54,55,56,57,58). These have drawn a mixed picture of success, stagnation and moving away from targets. Progress and failure of the programme has to be studied in detail and in the specific areas of intervention. Reported declining rates of health affecting items have been partly compensated by a consistent high level of incidents (e.g. injuries by fire arms). The evaluation reports are meeting high quality standards in a technical sense of view. The main question, if – in a political sense – the entire programme includes really sufficient tools in order to tackle the most obvious unhealthy conditions which are producing negative health effects in a broad range of target groups – is not be answered by the annual reports in a sufficient way. So there remains the main impression that the Healthy People Programme represents mainly a big size health monitoring activity with an attached target structure. In the meantime the year 2000 targets have been replaced by year 2010 targets (59) and accomplished by a set of instruments in order to facilitate the development and implementation of objectives and measures (60).

In **Germany** the development of a national health target programme was started in 1999. A consensus platform containing a broad range of actors was established, organised by the GVG (Association for Social Security Policy & Research), Cologne and sponsored by the German Federal Ministry of Health and Social Security, Berlin. A report on the starting activities was handed over to the Ministry in February 2003 (61).

The technical aspects of the German health target approach are presented in the Figure 2, which is an element of the internet presentation *gesundheitsziele.de* (62).

There is a number of other national target programmes or systems of health reporting which are using targets. There is one source of information which is to be recommended first: the 1998 „Review of Health Target and Priority-Setting in 18 European Countries“ edited by TNO Prevention and Health, Public Health Division, Leiden/Netherlands (63,64). The 18 countries included in the study are: Austria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, The Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Switzerland, United Kingdom (64). Other sources that give a sound survey of a broad range of European target approaches are: a reader, edited by *Marshall Marinker* (65), and a newsletter, published by MSD pharmaceutical company (66).

Figure 2. Main aspects of the German national health target programme

Some further regional target programmes

In the international debate on health targets the **Quebec** programme *"Policy on Health and Well-Being"* is one of the most regarded regional health target approaches. The ambitious 1992 programme is characterised by a policy focusing on health and social organisation. So the main aspects of the implementation strategy are lieing in the aspects:

(i) encourage the reinforcement of the individual's potential;

(ii) provide support in social settings and develop healthy and safe environments;

(iii) improve living conditions;

(iv) act for and with groups at risk;

(v) coordinate public policy and action to promote health and well-being;

(vi) orient the health and social services system towards the most effective and least costly solutions.

The Quebec programme contains 19 targets which are related to five areas: social adjustment; physical health; mental health; public health; and social integration (67).

The first regional health target programme in Germany was developed in **Hamburg** (68,69). It was published in the year 1992 as an inconspicuous part of a health report of the *City of Hamburg,* which represents a state of its own in Germany with a 1.7 million population. The 14 targets focused on child health (69). Hamburg succeeded in publishing an additional evaluation report in 1994 (70)**,** which had been reflecting a reasonable number of successful measures in order to empower the health state of the target group of the programme – with a focus on the social situation of children and adolescent persons (71). In 1998 the Hamburg health target programme became a prize winner in a nationwide competition on health targets ("Berliner Gesundheitspreis") in Germany.

Another early approach by a German federal state is the **Sachsen-Anhalt** health target programme (72). Published in 1997 – embedded in a regional health report similar to the Hamburg approach – a number of five targets was presented. The topics are: infant mortality; grade of vaccination; mortality on cardiovascular diseases; cancer; consumption and effects of alcohol and tabacco. The Sachsen–Anhalt approach was started by an initial health policy conference. It is backed by five expert taskforces. Presently the target programme is under organisational reconstruction.

Selection of local health target programmes

Local health target programmes are usually developed in reference to the WHO *Health for all strategy*. Cities can also become member of the WHO induced *Healthy Cities Network*. An early example for this type of synergism is given by the programme of **Sandwell**, a community located near Birmingham/ Great Britain. The ambitious target programme of the 300,000 population community is dating from 1989 and is similar to the WHO's *Health for all* paper. An interesting detail of this approach is that Sandwell is a multicultural community with about 15 % people from Asian descent. So there is a high attention to health inequalitity issues influencing the outfit and the details of the programme (73,74,75).

Another ambitious local approach can be reported from Canada: **Edmonton**, a 666,000 population city released a programme „Health goals for Edmonton" in 1992 (76). The framework of this activity is set by the *Healthy Edmonton 2000* project. The 54 goals are covering five areas of action:

1. maximising life expectancy
2. reducing risks to health

3. improving health services

4. removing inequalities in health

5. creating a healthy environment.

The goals are titled by the slogan „direction for success # x“ (e.g. x = 51 means *Improving Drinking Water*) and they are linked with a series of concrete measures (called „opportunity for action“). Like other target programmes the Edmonton approach contains a lot of details and health data which are underlining the need for action in the five areas mentioned above. In this way the Edmonton approach represents the wellknown cooperative scheme driven by a tight linkage of health monitoring resp. reporting issues and health promotion concepts.

A relatively young local health target programme has been developed in ***Bielefeld/***Germany (population: 300,000): based on the results of an expert workshop in 1999 and on a representative survey about health service outcomes in Bielefeld and their perception by citizens in the year 2000 an expert group started to work out a target programme. Three global targets have been set out in detail:

1. “A health sector which is addressing the needs of the population“ (= „Bürgerinnen- und Bürgerorientierung“);

2. “Equity in health aspects“;

3. “Prevention and health promotion“.

All of these three global targets are linked to similar target formulations of the WHO *Health for all 2000* resp. *Health 21* programme. In addition the Bielefeld global target # 1 is linked to the North-RhineWestphalian target # 8; the Bielefeld global target # 3 to NRW‘s target # 3 (*see above*). The Bielefeld target programme has been released by the city council in Summer 2003. The next steps will be working on concrete objectives and measures in order to implement these global targets in priority areas with need for intervention (77).

Figure 3. Number of areas, targets, objectives – in a selection of 14 health target programmes

Overview : selected target programmes

	Areas	*Objectives*	*Targets*
WHO	**5**	**38**	**approx. 250**
Finland	**5**	**34**	**?**
England	**5**	**25**	**25**
USA	**22**	**approx. 330**	**approx. 600**
Australia	**4**	**83**	**?**
Québec	**5** (+3)	**19**	**77**
Wales	**10**	**180**	**180**
Catalonia	**13** (+15)	**approx. 600**	**approx. 600**
Oestergoetland	**4**	**26**	**26**
Hamburg	**5**	**14**	**14**
NRW	**5**	**10**	**approx. 60**
Berlin	**3** (+1)	**19**	**approx. 45**
Edmonton	**6**	**54**	**90** (318)
Sandwell	**5**	**38**	**73** (100)
Region	***Zielbereiche***	***Einzelziele***	***Teilziele***

Source: Welteke R. North Rhine-Westphalia's health target concept compared at the European and international level [computer file]. Bielefeld, London; 1997.

Figure 4. Preferred areas and grade of quantification – in a selection of 14 health target programmes

	Diseases & epidm. asp.	Social affairs	Environmt. hygiene	Caresystem	Economis	Acci-dents	Grade of quantific.
WHO	●●●	●●●	●●●	●●●	●	●●	●●
Finland	●●●	●●	●●●	●●●	●●	●●	?
England	●●●	(●)	○	○	○	●●	●●●
USA	●●●	(●)	○	○	○	●●	●●●
Australia	●●●	(●)	○	●	○	●●	?
Québec	●●	●●●	○	●●	●●	●●	●
Wales	●●●	●●	●●●	○	●●	●●	●●
Catalonia	●●●	(●)	●	(●)	○	●●	●●●
Östergötl.	●●	●●	○	●●	○	●●	●●
Hamburg	●●	●●●	○	●●	○	●●	●●
NRW	●●	●●	●●	●●●	●	○	*optional*
Berlin	●●●	●●	●	○	○	●●	●●
Edmonton	●●	●●●	●●	●●	(●)	●●	●
Sandwell	●●	●●●	●●●	●●●	(●)	●●	(●)

Source: Welteke R. North Rhine-Westphalia's health target concept compared at the European and international level [computer file]. Bielefeld, London; 1997.

Key:

A. Preferred areas

●●● *main area* (several or many objectives)
●● *presented area* (at least one objective)
● *only occasionally mentioned* (target)
(●) *only occasionally mentioned* (context)
○ *not mentioned, but cross-sectional item*

B. Grade of quantification

●●● *all targets*
●● *most of the targets*
● *only some of the targets*
(●) *no evidence*
? *not examined*

How to develop a target programme

Different types of target programmes

An empirically based analysis of existing target programmes leads to at least two different approaches to the task of developing a target programme:

a) the health monitoring based approach

This is the way, which had been chosen by *Catalonia* and by *Wales* – for example. There has also been a proposal produced by a German research unit led by *Karl E. Bergmann*, Berlin (78), which presents the steps of this approach in a convincing way**: *first,*** bring up a broad range of health monitoring facts – preferably organised in a matrix of health indicators – ***second,*** try to identify a comparable system of data, which allows you to start a benchmarking procedure. In Germany this approach has been realised e.g. by *Sachsen-Anhalt*, which has compared the health monitoring findings within its population of 2.7 million with the national health data of the Federal Republic of Germany (72). This benchmarking procedure opens the opportunity to reveal a special pattern of (regional) health problems. The findings may be helpful to start the process of a political adjusted decision making process, which means the ***third*** step of this procedure.

b) the policy centered approach

This procedure is based on the inverse sequence of steps of the approach which is described above under a). The ***first*** idea is a political incentive in order to introduce some change in the health policy landscape of the region or nation. Usually there are a lot of topics and problems which can be easily identified as appropriate to be introduced into a setting of health targets. There seems to be no urgent need for building up a comprehensive and long term oriented quantified data system. Usually there is the feeling of having enough evidence to make these topics valid in order to be chosen for a target. Sometimes an *ad hoc* data collection is carried out to produce an empirical base. Systematic aid in establishing such a policy centered health target system can be lent by other existing health target approaches.

The WHO target approach *„Health for all“* has been the fostering health target model # 1 for this type of policy centered national or regional health target systems. As there had been a broad consensus of the nations of the European region to release the *Health for all* target programme there was nearly no threshold to use the prepared technical inventory of targets, strategies, and measures of the WHO programme. On the other hand the WHO

programme itself has to be characterised as a primarily policy centered programme: the first paper versions of the 1995 edition had been including an annex with a series of health indicators. But it was obvious that there was a need for a thoroughly carried out working package to make this empirical tool suitable for health monitoring purposes. Actually, this ***second*** step of establishing an indicator programme which is capable to meet evaluation needs is the difficulty of this approach b.

Networking for pragmatic support

A realistic and pragmatic approach in order to build a target programme needs a sufficient technical support. The idea of networking to get a start up has led to a cooperation – e.g. the WHO associated *Healthy Regions Network*, which was presented above. If there is a national or regional health target programme usually support is given to local authorities, if they are starting their own target setting process. A special example of support is given by the U.S. Healthy people 2010 toolkit, which is available via internet:

Figure 5. Action Areas of the Healthy people 2010 toolkit

Building the Foundation: Leadership and Structure
Identifying and Securing Resources
Identifying and Engaging Community Partners
Setting Health Priorities and Establishing Objectives
Obtaining Baseline Measures, Setting Targets, and Measuring Progress
Managing and Sustaining the Process
Communicating Health Goals and Objectives

Source: Healthy people 2010 toolkit. Available from: URL: http://www.healthypeople.gov /state/toolkit/default.htm

Another toolkit is to be provided by WHO for the end of 2003 (at the WHO Europe website http://www.who.europe.dk)

Diagnostic tools

Especially for the purpose of starting development of local target programmes there are some points of interest which should be taken in account. Three checklists may be helpful in order to get some more evidence for an expected sucess of a planned target programme (79):

Figure 6. Implementing checklist # 1

• Implementing of local health target programmes - **10 promoting elements**:
1. existing (and working) health monitoring and reporting system 2. actors with motivation to be successful in achieving health gains 3. communication platforms for actors involved 4. decision making process open for participation of patients and citizens 5. priority related discussions and steering of resources 6. transparency of political decisionmaking 7. sufficient criteria and tools for programme assessment 8. transparency in setting assessment criteria 9. shared responsibility for programme management and results 10. transparency and media support to programme development and assessment

Figure 7. Implementing checklist # 2

1. more than 7 (of 10) points positive in checklist # 1 2. working interaction and/or professional management of the components of checklist#1 3. acceptance and support by local politicians and activity groups 4. positive motivation of actors and users of the target programme
• Implementing of local health target programmes - **7 steps to be successful**
5. promotion of target setting and implementing attempts by regional and/or national

Figure 8. Implementing checklist # 3

• Implementing local health target programmes - **8 final questions**:
1. do the health monitoring and reporting tools really work? 2. do the actors really want to be successful with the programme? 3. are the actors ready to communicate and to cooperate? 4. is there a policy of participation? or: is it possible to introduce participative components into local policy? 5. is there any (political) discussion on priorities in health aspects? 6. is there an opportunity for negotiation of criteria for assessment of the programme? 7. is there enough of common sense among the actors who are backing the programme? 8. is there a chance for using public relations and local media for promotion of the programme?

Some final remarks

This presentation of health target programmes and approaches is the attempt to give some information about a field of activity which is characterised by a high level of heterogenity. Out of the variations in programme performance and in dynamics of implementation arise additional difficulties for proper analysis. Last but not least health targets are usually part of a policy programme. And policy programmes are almost mixed up with some advertising components. So it is not easy to get a sufficient degree of transparency in the present situation and to give some valid remarks on the state of the art. The ambiguity of the subject is recorded by a fine dialogue "For and against health targets", which is really worthwhile reading for those who like the flavour of dialectics and who want to get some more ideas and literature references related to this delicate topic. "I find nothing intrinsically wrong with setting targets and goals but unless these targets are accompanied by strategies to achieve them they may in the long term, because of repeated failure, do more harm than good. Being in favour of something is of itself inadequate.... Scepticism is the scalpel which frees accessible truth from dead tissue of unfounded belief and wishful thinking" (80).

Despite of this kind of scepticism, which undoubtedly has some realistic background, the motivation, the professionalism, the personal beliefs, the enthusiasm of many acting persons and institutions in the field of health targets are evident and impressive. This is encouraging indeed for everybody who gets in contact with these activities. On the other hand health targets are something of the category that means "tool", instrument or part of a "procedure" or "system". This side should be lead to a more realistic view: health targets are only one instrument in a pool of a variety of others.

And sometimes, especially if things do not work well for some time, it gets obvious, that the developing and implementing procedures of health targets are facing similar problems as tools, instruments, and related procedures; like health monitoring and reporting, like health promotion, like health impact assessment, like public health research activities, which are also facing problems in their performance from time to time.

All of these tools (in a broader sense) are dealing with the human health and they are ambitious attempts to strengthen the role and the performance of human health. But: they remain to be tools, instruments and usually they stay a little bit apart of that what really means health, health "for the people". But sometimes, in special situations, these tools become important: there are upcoming situations which require valid and effective

tools – in the right moment, on the spot. Although health target programmes are instruments developed for the long term performance – sometimes there is the impression, it would be sad if all this energy was not put into the health targets process. So – this may be a little too much impassioned closing remark – but: why not?

EXERCISE: Health Targets

The purpose of exercises are given below, through objective, methodology and description of each task. Time needed for exercise is approximatly 4,5 hours.

Task 1: Objective of this task is identification of health targets based on health monitoring data, through group working, statistical analysis, and discussion.

Students can work in small, country-based groups. They should try to identify problems according to health monitoring data, calculate indicators and build up measurable and valid targets appropriate for their own country. They should develop a discussion about challenges of realisation of identified health targets within local political situation (recommended usage of Implementing checklist 1). At the end they should make written comments.

It is recommended to use comparable health statistical reports. Use Internet sources, too.

Timing: 1,5 hour of students work.

Task 2: Objective of this task is identification of national/international health targets (if any), and comparison with their own health targets, through group working, statistical analysis, and discussion.

Students can work in small country based groups. They should search for their national health targets, compare with their own and make comments. The comparison can be made on international level. Comments should be written.

Students should use Internet sources.

Timing: 30 minutes for students.

Task 3: Objective of this task is implementation of health target programme and usage of diagnostic tools for evaluation, through individual work and analyses of local health policy.

Every student will get previously prepared example of health target programme with defined targets but one with health monitoring based approach and the other with policy centred approach. The task will be identification of action areas in local conditions (usage of Action Areas of the Healthy people 2010 toolkit http://www.healthypeople.gov/state/toolkit/default.htm is recommended), diagnosis of implementation of target program in local region by usage Implementing checklist # 2 and # 3. They suppose to write a report about possibilities of realization of such programme and describe problems which they can find during analyses.

Timing: 2,5 hours for students.

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Internet Linkpage

Linkpage 7.1. Health Targets – International and National :

Australia

http://www.health.qld.gov.au/publications/infocirc/info28.pdf

http://www.rmit.edu.au/departments/ps/assid/health.htm

Canada

http://www.hc-sc.gc.ca/english/media/releases/2001/tobaccotax_2001ebk.htm *(Tobacco)*

Eire/Ireland

http://www.issi.ie/naps/summary_resource_material.htm *(Social inequalities)*

Europe

http://www.who.dk/eprise/main/WHO/Progs/HPA/Targets/20020319_1 *(WHO Europa)*

http://www.who.dk/observatory/Publications/20011008_4

(Seite wird nicht automatisch per LINK angezeigt) daher à http://www.who.dk/

Germany/Deutschland

http://www.gesundheitsziele.de

Great Britain/United Kingdom

http://www.foe.co.uk/resource/reports/uk_progress_who_targets.pdf

http://www.nwpho.org.uk/inequalities/Life_expectancy_HAs.pdf *(Health Inequalities Targ.)*

http://www.ohstrategy.net/strategy/targets.shtm *(Occupational Health Targets)*

http://www.mbha.nhs.uk/annual_reports/PH1996/ph96-4.htm *(evaluation)*

Lithuania

http://www.sam.lt/reform/objectives.htm

Poland

http://www.medstat.waw.pl/nhp/0.html#2

United Nations (UN)

http://www.un.org/esa/socdev/ageing/agetarg.htm

http://millenniumindicators.un.org/unsd/mi/mi_goals.asp

United States of America

http://www.crisny.org/health/us/health7.html *(Healthy People 2000)*

http://www.health.gov/healthypeople/state/toolkit/default.htm *(Healthy People 2010 -Toolkit)*

http://www.health.gov/healthypeople/state/toolkit/progress.htm *(Healthy People 2010-Toolk.)*
http://www.healthierus.gov/ (President's HealthierUS Initiative *)*

http://www.healthypeople.gov/Document/tableofcontents.htm

http://www.hhs.gov/news/press/2001pres/01fsasthma.html *(Combating Asthma)*

World Bank

http://www.developmentgoals.org/Research.htm *(Health Targets)*

World Health Organization (WHO international, Geneva)

http://www.who.int/whr/1998/whr-en.htm

Linkpage 7.2. Regional Health Targets:

Alberta (CDN)

http://www.health.gov.ab.ca/rhas/rhatarge.htm

Essex (GB)

http://www.ne-ha.nthames.nhs.uk/hsp/13.htm#top

Lower Saxony/Niedersachsen (D)

http://www.gesundheit-nds.de/frames/arb_schwpkte/a_schwpkte.html#Anchor_4
(Gesundheitsziele im Rahmen des Modellprojekts „Gesundes Land Niedersachsen)

North Rhine-Westphalia/Nordrhein-Westfalen (D)

http://www.google.de/search?q=Gesundheitsziele&hl=de&lr=&ie=UTF-8&start=60&sa=N
(Ausschnitt Ziel 3)

http://www.glueckksspielsucht.de/materialien/LANDES1D.pdf *(zu Ziel 4)*

http://www.mfjfg.nrw.de/aufgaben/gesundheit/gesund.htm *(Gesundheitsministerium NRW)*

http://www.dshs-koeln.de/soziol/gbe/Einleitung.htm *(Kreis Neuss)*

Oberösterreich (AU)

http://www.ooe.gv.at/alz/alz2000/01/08.htm

http://www.sggp.ch/gpi/archiv/ghbericht_1-02.cfm

Sachsen-Anhalt (D)

http://www.asp.sachsen-anhalt.de/presseapp/data/ms/2002/034_2002.htm

Schleswig-Hostein (D)

http://www.schleswig-holstein.de/landsh/mags/gesundheit/gesundheit_13.html

Schottland (GB)

http://www.show.scot.nhs.uk/achb/about/Targets.HTM

http://www.ihmscotland.co.uk/Conferences/DEc%202001/Practice%20Mx%20Conf/sld012.htm

http://www.scotland.gov.uk/library/documents/oral03.htm *(oral health targets)*

South-Australia (AUS)

http://www.dhs.sa.gov.au/pehs/ *(à http://www.healthysa.sa.gov.au/)*

Steiermark (A)

http://www.landeshauptmann.steiermark.at/cms/ziel/256871/DE/

http://www.aekstmk.or.at/medien/02042002.htm *(provisorisch)*

Victoria (AUS)

http://www.dhs.vic.gov.au/phd/hdev/hpromo/funding/nattar.htm

Wales (GB)

HEALTH TARGETS AND INDICATORS: A CONSULTATION DOCUMENT

HTML-Version www.hpw.wales.gov.uk/english/resources/reportsandpapers/
health_improvement_document_e.doc - Ähnliche Seiten

http://www.dyfpws-ha.wales.nhs.uk/Compendium2000/page21.html *(1995 – 1998 – 2010)*

http://www.dyfpws-ha.wales.nhs.uk/compendium2001/page33.html

Linkpage 7.3. Selected publications on Health Targets:

Australia (AUS)

http://www.nisu.flinders.edu.au/pubs/monitor7/mon7p7.html

http://www.nisu.flinders.edu.au/pubs/monitor10/monitor10-Metamorp.html

Germany/Deutschland (D)

http://www.infodienst.bzga.de/medien/01_12/mabuseziele.htm

http:// www.loegd.nrw.de

http://www.dfi.uni-duesseldorf.de/main/04aktuelles/StVincent.shtml ***(Diabetes – St. Vincent)***

Great Britain/United Kingdom (GB)

http://www.dur.ac.uk/comparative.publichealth/research/bmj.htm

Nigeria

http://www.aegis.com/news/ips/2001/IP011217.html *(AIDS)*

North Rhine-Westphalia/ Nordrhein-Westfalen (D)

http://www.loegd.nrw.de/publikationen/ref/refgpolitik.html

http://www.loegd.nrw.de/publikationen/ref/refgpolitik.html

http://www.loegd.nrw.de/loegd_english/services/health_policy.html

http://www.infodienst.bzga.de/medien/01_12/mabuseziele.htm

http:// www.loegd.nrw.de

HEALTH SYSTEMS AND THEIR EVIDENCE BASED DEVELOPMENT A Handbook for Teachers, Researchers and Health Professionals	
Title	**Health Legislation: Procedures towards Adoption**
Module: 3.4	**ECTS (suggested): 0.25**
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Keywords	Regulations, legislative procedure, health legislation, health law
Learning objectives	At the end of this module, students would become familiar with the classification of legal regulations as well as the legislative procedure. They will increase their knowledge about: • different types of legal regulations, recognising the differences among them; • legal procedure in their own country; • legal areas, in which in their own countries legal regulations relating to health and health care could be found; and • the media by which the adopted laws (acts) and other adopted legal regulations as well as the obligatory explanations come into operation.
Abstract	The public health professionals should be at least roughly familiar with different types of legal regulations and the procedures for adopting them. Their possible professional role could be among others also to propose a new law or other legal regulation to an appropriate legislative body, which is responsible to adopt it or to propose the amendments or changes to already adopted laws or other legal regulations. This module is aiming at students to get familiar with the classification of legal regulations as well as the legislative procedure (the Republic of Slovenia example). Also some contents, regulated by health legislation are described.
Teaching methods	The teaching method recommended by the author is a combination of introductory lecture, group work and final discussion. Detailed description of steps is given.
Specific recommendations for teacher	It is recommended that the module should be organized within 0.25 ECTS credit. Students are asked to collect some of the readings - Health Care Law, Health Insurance Law or „national digest of legislation" by themselves. If there are students with different undergraduate background in the group they should be divided to smaller group according to this.
Assessment of students	The final mark should be derived from assessment of practical work and from assessment of theoretical knowledge of the student. A detailed description is given as well as an example of a question (test type).

HEALTH LEGISLATION: PROCEDURES TOWARDS ADOPTION

Lijana Zaletel-Kragelj

The health legislation is the common term for all legal regulations which serve to human health. The areas, which are regulated by them, are very different. In one side for example we have the regulations, which refers to control various diseases and on the other side the financing of various activities related to human health. The function of health legal regulations is thus heterogeneous. The main function is to prohibit people's activities which are injurious to the human health (for example dumping of toxic chemicals in the environment or spreading the infectious diseases), to authorize health programmes and health services (for example authorizing of health services for mothers and children), to regulate the production of resources for health care (for example financing the construction of outpatient departments or hospitals), to provide the financing of health care (health insurance) and to authorize surveillance over the quality of health care (minimum standards for health personnel and facilities) (1). But with no regard to the content of specific legal regulation, all regulations and the procedures for adopting them are subject to common principles.

The modern public health professionals should be active and creative also in this field, regardless of their basic profession. Their possible professional role could be among others for example also to propose a new law or other legal regulation to an appropriate legislative body, which is responsible to adopt it or to propose the amendments or changes to already adopted laws or other legal regulations. This module thus focuses to the basic knowledge on legal regulations with special emphasis on health matters.

Classification and short description of the legal regulations

Classifications

There are several different types of legal regulations known. They could be roughly classified by two classifications (2).

Classification 1:

- General legal regulations – regulations that don't define the number of the subjects in advance;

- Individual legal regulations – regulations referring to the subject that is exactly defined;

Classification 2:

- Abstract legal regulations – regulations referring to the simulated cases (Constitution, laws...);
- Concrete legal regulations – regulations referring to the existent concrete circumstances in which the legal subjects are asked to behave and act in a specific way.

Mostly the general abstract legal regulations are used in common.

General abstract legal regulations

Among this kind of regulations we can find constitution, laws and statutes (2).

1. Constitution. Constitution is the most fundamental regulation that regulates the substance that is of essential importance for the certain country and its society. It is adopted by Parliament (National Assembly).

2. Laws. Laws are general legal regulations that regulate the substance that is principal and fundamental for the certain legal system. But at the same time the substance is not so important to be regulated by the Constitution. They are adopted by Parliament (National Assembly).

3. Statutes. Statutes are legal regulations with less significance then the laws. There exist several statutes. The following ones are listed by the order of legislative body that adopts the particular statute:

- Decree – regulates and analyses relations that are defined by the law. It is adopted by the government.
- Ordinance – regulates individual issues and stipulates provisions that have a general meaning (is more detailed than a decree). It is also adopted by the government.
- Regulation – regulates the organisation of the operation or the method of the proceeding of the specific body. It is adopted by the minister.
- Order – intended for the implementation of the individual provisions - it orders or interdicts the operation that has a general meaning. It is adopted also by the minister.
- Instruction – it regulates the method of proceeding of the administrative body that executes individual provisions of the law or the statute. It is adopted also by the minister.

The legislative procedures

The legal regulations are adopted by the official procedures, regulated by special legal acts, which regulates functioning of particular country (3). These procedures are more or less similar for majority of the countries. As an example a procedure for adopting a law will be described as follows, as laws are the main legal regulations immediately after the constitution.

The process of a law becoming official is called "enactment". Also the law that has been passed by the official procedures (for example in a parliament of a country) is called no longer "a law" but "an act".

The procedures for enacting a law: the Republic of Slovenia case

In Slovenia the procedure for enacting a law is regulated by Rules of Procedure of the National Assembly (the Parliament of Slovenia) (4,5). This procedure can be divided to a regular procedure or fast-track procedure. Also every law can be reconsidered as well as an obligatory explanation of every single law can be made.

Regular procedure

The regular procedure has several phases: proposal of law, first reading of a proposed law, second reading of a proposed law, third reading of a proposed law and voting on a law. In following section of the module the most important parts of single phase of this procedure are described:

1. Proposal of a law

Every law can be proposed by the government itself, every deputy, a group of at least 5,000 voters or by the National Council.

The proposal of the law must contain the title of the law, an introduction, the text and an explanation. It must contain the reason/s for enacting the specific law, its goals and principles, an estimation of the financial burden for the national budget, required for its enactment. It is to be sent to the president of the National Assembly. The president than forward the proposed law to deputies, to the National Council and to the government, when the latter is not the proposer of the law.

The President of the National Assembly determines the primary standing committee to participate in the debate of a proposed law and report to the National Assembly and when the proposed law contains provisions which require funds from the national budget, the president shall also assign such law for

debate to the standing committee competent for financial matters. The standing committees are working groups which study individual fields, prepare decisions on policy in these fields, formulate opinions on individual questions, and prepare, study and debate proposed laws and other acts of the National Assembly.

A proposed law is then discussed by the National Assembly in three readings. The secretariat for legislation and legal affairs shall offer, at each reading of a proposed law and before the voting on the law, an opinion on the conformity of the proposed law with the Constitution and with the legal system, and proposals in relation to the legal and technical treatment of the law.

The proposer of a law may withdraw the proposed law up until the conclusion of the second reading.

2. First reading

During the first reading of a proposed law, its presentation in the National Assembly and then a debate on the reasons demanding its enactment and also on the principles and goals is held.

The primary standing committee presents its opinion on the law, which could be positive or negative. If it is negative, the standing committee ought to formulate its own proposal for a decision which the National Assembly should adopt after the conclusion of the first reading. If it is partially negative, the standing committee may formulate a proposal for opinions which the proposer should take into consideration in the preparation of the proposed law for its second reading.

At the end of the first reading of a proposed law the National Assembly has to decide:

- To hold a second reading of the proposed law at the same or the following session with the text as submitted for the first reading, or
- That the proposer of the law or the secretariat for legislation and legal affairs shall, within a given time limit, prepare the text of the proposed law for its second reading in accordance with the opinions of the National Assembly adopted at the conclusion of the first reading, or
- Not to enact the law.

If, after the conclusion of the first reading, the National Assembly decides that the second reading of the proposed law shall be held, it defines the time of the second reading. If it decides not to adopt the law, the legislative procedure is terminated.

The text of a law prepared for its second reading must contain explanations indicating in which articles and in what way the opinions of the National Assembly have been taken into consideration.

During the first reading it shall not be possible to propose amendments to individual provisions of the law.

3. Second reading

During the second reading of a proposed law, the National Assembly debates each article of the law in the order of articles and then its title. When the National Assembly concludes the debate on an individual article, deputies vote on it. At the end they also vote on the title of the law.

At the proposal of the primary standing committee, a deputy group or at least ten deputies, the National Assembly may decide that the second reading of a proposed law shall be conducted as a general debate on it or that the first reading shall be repeated.

During this phase of the procedure, deputies, the primary standing committee, an interested standing committee and the proposer may submit amendments to propose the changes and supplementations to the proposed law. The government may also propose an amendment when it is not the proposer of the law.

The primary standing committee shall state its opinion on an amendment/s. This opinion is a part of the report on the proposed law submitted by the primary standing committee to the session of the National Assembly. This report shall also contain a report by the secretariat for legislation and legal affairs if the secretariat for legislation and legal affairs submitted an opinion in the debate on the amendment in the primary standing committee.

Deputies shall vote separately on each amendment to a proposed law. If several amendments are proposed to an article of a proposed law, deputies shall vote first on the amendment which departs most from the content of the article in the proposed law, and then, following this criterion, on other amendments. If also an amendment is proposed to an amendment, deputies shall vote first on the amendment to the amendment.

If, during the second reading, no amendments were adopted to the text of the proposed law or only amendments of an editorial nature in the opinion of the secretariat for legislation and legal affairs, the National Assembly may, at the same session, continue on to the third reading of a proposed law. If amendments were adopted during the second reading, the third reading is to be conducted. The secretariat for legislation and legal affairs shall prepare for the

third reading of the proposed law the complete text of the proposed law with adopted amendments and with an explanation of changes in the wording of articles submitted for the second reading. The National Assembly may assign this task also to the proposer of the law.

4. Third reading

During the third reading of a proposed law, the National Assembly has to debate the proposed law in its entirety. The separation of individual articles of the proposed law is possible only for the articles which were altered with amendments during the second reading. During this phase of the procedure an amendment also may be proposed. The procedure is the same as in second reading. The primary standing committee shall again present its opinion on the proposed law.

5. Voting on a law

At the end of regular procedure, the National Assembly has to vote on the proposed law in its entirety. A law is enacted if the number of votes cast "for" is greater than the number of votes cast "against", unless a different majority is provided for the enactment of a law by the Constitution or by law. The secretariat for legislation and legal affairs has to prepare the final text of the law (the original) on the basis of decisions made by the National Assembly.

Fast-track procedure

In certain special circumstances it is also possible to enact a law by using the fast-track procedure. These special circumstances are extraordinary needs of the state, the interest of defence, or circumstances of natural disasters. Such proposal must be specifically explained.

If the National Assembly determines to use the fast-track procedure, it has to merge all three readings of the regular procedure in one session.

Reconsideration of a law

Before the official proclamation of the law, the National Council can impose to the National Assembly its reconsideration. The president of the National Assembly has to forward the request of the National Council to the primary standing committee. The latter shall formulate an opinion on the content of the request by the National Council. The National Assembly shall conduct the vote of reconsideration at its next session. A law is enacted if the majority of deputies of the National Assembly vote for it unless provisions of the Constitution require a greater number of votes for enactment of a law.

The procedure for the obligatory explanation of law

For every law an obligatory explanation of a law also could be made. This explanation could be proposed to the National Assembly by any of those having the right to propose a law (the government, every deputy, a group of at least 5,000 voters, the National Council). The procedure is similar to the regular procedure for enacting a law.

Publication of adopted legal regulations

The adopted laws and other adopted legal regulations as well as the obligatory explanations are published in Slovenia in the Official Gazette of the Republic of Slovenia (Uradni list Republike Slovenije). Every year also the register of current legal regulations is published (3).

Prior to the adoption and prior to the publication in the official gazette every law in Slovenia could be found in the Bills database, attainable at the National Assembly Website (6). The Bills database contains bills in the current term which are in parliamentary procedure (regular, fast-track procedure...) and in one of the readings (first, second, third) in the National Assembly.

Ratification of international treaties

There exist numerous legal regulations related to health and health-related matters at the international level. Every country has its own procedure to accept or to ratificate such regulations.

In Slovenia the National Assembly ratify every international treaty with a special law. The provisions of the fast-track procedure for adopting a law are used.

The contests, regulated by health legislation

As it was already mentioned in the introduction that there are many different problems relating to the peoples' health. Because of this reason the content of legal regulations relating these problems is very diverse. They can regulate for example the control over communicable or noncommunicable diseases as well as health financing, health research, health insurance, functioning of health care institutions, ethical issues, health professional's responsibilities and many others. It is very difficult to make a one uniform classification of all the health and health care relating legal regulations as these regulations could be found in several legal areas: mostly in health care and health insurance area,

but also in the other areas as agriculture, forestry, nutrition and food, poison and other hazardous substances, occupational health and safety, environmental protection, radiation protection and many others. The distribution of health related legal regulations among legal areas depends also on the single country.

Review of health legislation in Slovenia

In Slovenia health related legal regulations could be classified according to several health spheres. The following classification is according to Ministry of Health of Republic of Slovenia (only the most important acts are listed):

1. Health care and health insurance sphere:

- Health Care and Health Insurance Act
- Infertility Treatment and Procedures of Biomedically-assisted Procreation Act
- Repayment of Harm to Individuals with HIV Infection due to Blood Transfusion or Transfusion of Blood Preparations
- Removal and Transplantation of Parts of Human Body for the Medical Treatment Purposes
- Restriction of the Use of Tobacco Products Act
- Health Care of Foreigners in Republic of Slovenia Act
- Health Interventions for Fulfilment of Right on Free Decision-Making on Birth of Children Act
- Occupational Safety and Occupational Health Care Act
- Restriction of Alcohol Consumption Act

2. Health services and health activities sphere including pharmaceutical sphere:

- Health Activities Act
- Health Inspection Act
- Healthcare Databases Act
- General Practitioners Act
- Pharmacy Activities Act
- Natural Remedies and Natural Health Resorts Act

3. Medicinal products and medicinal devices sphere:
    - Medicinal Products and Medicinal Devices Act
    - Supply of Blood Act
    - Phytopharmaceutical Remedies Act
4. Cosmetics sphere:
    - Cosmetics Act
5. Food control sphere:
    - Sanitary Suitability of Foodstuffs, Products and Materials Coming into Contact with Foodstuffs Act
6. Communicable diseases control sphere:
    - Communicable Diseases Act
7. Chemicals sphere:
    - Chemicals Act
    - Chemical Weapons Act
    - Manufacture and Trafficking of Asbestos Products and Financial Assurance for Rearrangement of Asbestos Manufacture to Non-asbestos Manufacture Act
8. Humanitarian organizations sphere:
    - Red Cross of Republic of Slovenia Act
9. Illicit drugs sphere:
    - Manufacture and Trafficking of Illicit Drugs Act
    - Prevention of the Use of Illicit Drugs and the Treatment of Drug Users Act
    - Illicit Drugs Components Act

There exist also other legal regulations in Slovenia that contain parts highly related to health of human beings - for example Veterinary Medicine Act, Environment Protection Act etc.

EXERCISE: Health Legislation – Basic Knowledge

In order to fulfil objectives and according to the ECTS credit, student are expected to work individually for 2.5 hours (Task 1) and then discus in small group about legislation in their countries (Task 2).

Task 1: Preparing individually. Students are asked to inform themselves before session. They are supposed to gather all acts which are considering Health System, by using "national digest of legislation". Students should make a list of laws, regulations and subregulations, also be familiar with some basic laws, such as Health Care Law, Health Insurance Law.

Task 2: Students are divided into small group, in order to discuss the differences between health legislation in different countries.

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5. Rules of Procedure of the National Assembly. The Bills Database. The National Assembly of Republic of Slovenia Official Website (in English Language): http://www.dz-rs.si/en/aktualno/spremljanje_zakonodaje/poslovnik/poslovnik.html

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Recommended Readings

1. Law, ethics, and challenges. In: Holland WW, Detels R, Knox G, Fitzsimons B, Gardner L, eds. Oxford textbook of public health. Volume 1. Oxford, Oxford University Press, 1997: 351-413.

2. Backes O, Stebner FA. Gesundheistrecht. In: Herrelmann K, Laaser U. Handbuch Gesundheitswissenschaften. Weinheim and Muenchen, Juventa, 1998: 753-777.

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