



# Ethical and Legal Aspects of Medical Screening for Early Diagnosis of Diseases. Prevention and Prophylaxis

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## Abstract

**Introduction:** The main priorities of the implemented health policies in the Republic of Bulgaria are directly aimed at preserving and improving the health of the population, providing equal access of patients to modern and efficient healthcare, promptness and quality, in compliance with the normative requirements of the offered health service. In this sense, the focus of these health policies is to prioritize prevention and prophylaxis of early diagnosis of diseases. It is much more reasonable to prevent the disease or to manage it at an early stage than to slow down the treatment until the pathological processes develop into severe or irreversible complications.

**Aim:** The aim of this systematic review is to investigate the effectiveness of existing legal acts governing the implementation of a common health policy in the field of health promotion and prevention. Another aim is to localize regulatory gaps and make relevant optimization suggestions.

**Materials and methods:** The analysis of this systematic review is based on a thorough review of the existing regulatory framework (statutory and regulative legislation, case law, European practice) that concerns public health. Articles focused directly on the issues of medical screening and public health in a national and global perspective have been studied.

**Results:** Two major legal acts, two regulations and strategies of the World Health Organization are considered. Suggestions for optimization of the control activity of the administrative bodies in the sector are presented.

**Conclusions:** From the analysis done, proposals for optimization of the existing legal framework in the sector of health-care were made. The proposals were made based on the results of the analysis of world trends regarding the methodology for state funding of medical screening for early diagnosis of diseases.

The issue in question is up to date and raises issues related to legislative regulation, moral, ethical and deontological principles to which the medical profession adheres, as well as the health policy that is followed by the Ministry of Health in this aspect.

## Key words:

health, healthcare, medical screening, health prevention

## INTRODUCTION

In today's society, issues of health promotion, prophylaxis and medical screening are increasingly the subject of dis-

cussion. They are undoubtedly priority issues in the concepts and policies of modern healthcare. Their conceptual nature is directly aimed at stimulating society, through

campaigning government policies, to act responsibly when it comes to general health prophylaxis and to seek medical help promptly in emerging indications of disease. In this sense, here we should make a practical distinction between the three approaches to health prevention and early diagnosis of diseases:

Health promotion - this is an up-to-date area, part of the strategy for practical actions aimed at preserving and protecting human health and good public health status as a whole. From a theoretical point of view, the concept includes elements of many sectors and scientific disciplines - mainly sociology, social psychology, medicine, pedagogy, economics and political science. Achieving a consensus on a commonly accepted definition of health promotion today seems difficult in terms of the complexity and versatility of its concepts and strategies as well as the multidisciplinary approach. The most commonly used definition is that set out in the 1986 Ottawa Charter for promotion of health, which defines it as "a process that makes it possible for people to increase control of their health, as well as its improvement and healing".<sup>1,2</sup> In practice, health promotion often complements or overlaps with the term health prevention. However, it would be difficult to place a sign of equality between the two terms, considering the scope of the elements that are implied in the two strands. When promoting health, the main focus is on preventing the circumstances and factors causing the disease. This is by its very nature achieved by:

- developing models in healthcare, focusing on specific factors affecting health, involving both the individual and society as a whole, to achieve full harmony between the environment and health.<sup>3</sup>
- improving the general standard of living of individuals in society;
- cooperation between the different government sectors, from central to local authorities, on matters regarding healthcare and safe and healthy living conditions;
- effective and specific involvement of the public (of its various groups) in defining health problems and taking decisions related to health threats;
- based on the assistance of medical specialists as one of the most important social actors in building and introducing health promotion.<sup>3</sup>

When discussing the issue of health promotion, emphasis is placed on the study of all aspects and circumstances of public life and the existence of a causal link between the general health status of the particular individual and the environment in which they live and develop. The aim is to eliminate all risk factors that are directly proportional to the health status of individuals. Particular attention is paid here to the concepts of building an appropriate health, social and environmental policy.

The basic principles set in the development of health policies related to health promotion can be derived as follows:

- performing a periodic expert analysis on overcoming the unfavorable factors present in the individual's living environment;

- developing concepts and conducting health policies that are directly aimed at strengthening the health of the population;

- Increasing personal responsibility and developing personal skills, knowledge and opportunities to strengthen individual and public health;

- building and development of appropriate infrastructure that influences health promotion.

## MATERIALS AND METHODS

In the Republic of Bulgaria, the National Center of Public Health and Analyses (NCPHA), which is part of the structure of the national healthcare system and is responsible for: protection of public health, health promotion and disease prophylaxis, provision of information for health management. In accordance with its core health protection and promotion activities, the Center examines the health status of the population and its relationship to environmental factors and living conditions; it conducts epidemiological studies and assesses the risk factors for chronic non-communicable diseases; it participates in the development, coordination and implementation of national programs and action plans as well as in international research programs aimed at strengthening public health (including mental, reproductive and sexual health). The Center performs intervention events and training seminars. It also performs an exposure and health risk assessment of the population regarding the impact of biological, chemical and physical hazards in the environment and the working environment and in food, drawing up appropriate recommendations; it monitors the nutrition and nutritional status of the population, and develops nutrition guidelines for specific populations. The Center manages, controls, monitors and coordinates information activities in healthcare; it develops and unifies medical-statistical documentation on the health status of the population and on the resources and activities of the medical institutions.<sup>4</sup>

Health education represents a process of formation of a healthy culture during the adolescent development of the individual. It is expressed through the acquisition of health knowledge, beliefs and behavior related to enhancing, maintaining and restoring individual and public health.<sup>8</sup> Most efforts, including financial ones, should be directed in this direction due to the fact that they will find a future beneficial expression in the mature life of the individual.<sup>5</sup> Looking at the issue from a moral and ethical angle, the formation of a high health culture among the population will inherently lead to a reduction in the overall number of people in need of medical care for a future period, and thus to a reduction in the overall budgetary costs that are formed in the sector "Health". In order to achieve optimal results in conducting health education, a cumulative approach should be taken from an individual, group and social dimension. Undoubtedly, it is also achieved through proper education on this topic at school and in other formal educational environ-

ments. Internationally the accepted term is “health education”<sup>10</sup>, whereas in Bulgarian there is a distinction between the health education in a formal and informal environment. By its very nature, it includes the following components: learning; systematicity of actions and their planning; impact on individuals and groups as well as the sick and the healthy in order to increase their competencies; voluntary participation - no coercion and pressure on learners, who fully understand and accept the actions undertaken in the framework of health education - and, last but not least, the interdisciplinarity of health education.<sup>1</sup>

Health protection is expressed in the existence of comprehensive legislative measures aimed at increasing positive health and creating a healthy living environment. By way of example, we will only mention that, until the cancellation of Ordinance 7 of 25.07.1992 on hygiene requirements for health protection of the settlement environment (old) in May 2017, complex environmental assessments were prepared by independent experts, who were approved by the Ministry of Health in one opinion of the relevant Regional Inspection for Preservation and Control of the Public Health (RIPCPh). The result of this assessment is the permission of the Minister of Health, which increases or decreases the hygiene-protection zone under consideration. After the annulment of the aforementioned Ordinance, the issue under consideration finds regulatory regulation in the provisions of Articles 16a, 16b, 16c and 19 of Ordinance No 36 of 21 July 2009 on the conditions and procedure for exercising state health control.

Health prophylaxis as a general concept oriented to the living environment is a set of measures to prevent the spread of risk factors and diseases and their complications among the population. The primary control body, whose control competence includes issues related to the protection of public health, is the Regional Health Inspectorate (RHI). At present, there are twenty-eight regional inspections on the territory of the country. The main scope of activity of RHI is to coordinate the interests of the Ministry of Health with the local interests at the district level and to exercise systemic control at the local level, consistent with the established health policy. RHI operates the so-called Regional Health Council. The main purpose of the Council is to support the activities of RHI with regard to the implementation of state health policy. The Council's activity includes the adoption of the annual analysis of the health status of the population. It examines and accepts proposals for provision of resources to health and medical institutions. It examines and accepts annual analyses of provided medical care, as well as the needs for medical care and resources. RHI, by its very nature, exercises control over compliance with the health requirements for sites of community importance, products, goods and activities relevant to human health and the factors of the living environment. The Council develops and negotiates, through state and municipal health establishments, the carrying out of free preventive counseling related to health prevention.<sup>5</sup>

When discussing the issue of a healthy living environ-

ment, we should pay attention to the so-called “premorbid” prophylaxis. In its essence, it is aimed at preventing the occurrence of risk factors among the population and preventing the establishment of social, economic and behavioral patterns of life leading to an increased risk of illness. An example of premorbid prophylaxis is the application of waste-free manufacturing technologies that protect the environment from chemical hazards and risk factors.<sup>10</sup>

#### **Prevention and prophylaxis of health. Medical screening.**

Health prevention - from a terminological point of view, prevention stems from the Latin term ‘*praeventio*’ and means ‘overtaking’, ‘warning’. In this sense, when talking about health prevention, we should bear in mind that this is an overhead process which is directly aimed at maintaining a common health environment for the individual in order to prevent undesirable consequences for his or her health. The term is broader and covers all health factors and processes that affect or may have an impact on the well-being of individuals. Through health prevention modern diagnostic methods for early detection of disease indications and the detection of causal link between the indications of the disease and the surrounding factors causing it (stress, polluted environment, poor quality of food, unhealthy lifestyle) are being promoted.<sup>6</sup> It is often the case that, through health promotion campaigns and localized disease indications, periodic symptom prophylaxis is undertaken to prevent the patient's health deterioration until healing is completed. This is undoubtedly the desirable and intended result which has a positive effect not only on the general health status of the individual but also on the budgetary stability of the system. The financial cost of treating a disease diagnosed at an extremely early stage in the health budget would be considerably lower (medication, clinical pathway, treatment period, etc.).

Prevention of individual health inherently represents a set of medical and non-medical actions that the individual undertakes and conducts in order to maintain or improve their general life status. It is aimed directly at preventing the risk factors causing illness and reducing their consequences (chronic illness or permanent disability) and premature death.<sup>8</sup> Here we first address the conditions of an asymptomatic clinical stage, namely the state of the individual's organism in which there are no clearly manifested clinical manifestations and clinical signs of the disease. In this line of thought, there is clearly a causal link between the lack of regular preventive measures by the individual and the deterioration of his / her general health status during their periodic absence.<sup>7</sup> This circumstance will undoubtedly lead to a condition of clinical illness or to a diagnosis at a late stage of the disease, which in many cases ends with death.

#### **The prophylactic activity is theoretically divided into several categories.<sup>9</sup>**

- primary prophylaxis encompasses society without dividing it into specific categories or groups. It is aimed at taking the earliest measures related to the possibility of blocking the onset of the disease. Its scope is wide-rang-

ing and includes vaccination, advice on rational nutrition, physical activity, etc.

- secondary prophylaxis - an active method aimed at early detection of the disease before the clinical symptoms are fully developed. As a result, early treatment is prescribed and conducted to improve the condition of the patient and reduce the incidence of severe symptoms and chronic illness. Subjects of secondary prevention are predominantly visibly healthy subjects with asymptomatic disease or early clinical stage. A reliable tool for early detection of the disease and the implementation of secondary prevention measures is to conduct medical screening.<sup>10</sup> This type of prophylaxis also applies to categories of individuals carrying certain genotypes predisposing to particular diseases or falling into a certain age category for which there is a progressive increase in the incidence – some examples are blood cholesterol levels, female cytology tests, mammography and / or breast ultrasound, studying PSA level for early detection of prostate cancer in men (over 50 years), etc.<sup>11</sup>

- tertiary prophylaxis - this type of prophylaxis is targeted at chronically ill or disabled people. Here the primary disease is localized and treated, but the prophylaxis aims to prevent other categories of concomitant diseases or other adverse effects of the disease or disability.

Prophylaxis as a means of early diagnosis in order to overcome or prevent illness and obstruct the possibility of severe pathological disability should be a top priority in all national health strategies and programs. In this sense, good practice can also be drawn from the European Union's health policies in the fields of vaccination, the fight against antimicrobial resistance, action to combat cancer and responsible food labeling. To stimulate and enhance the general health culture, the Union has set up a specialized body - the European Center for Disease Prevention and Control (ECDC), which evaluates and monitors emerging health threats.<sup>11</sup>

Medical screening is part of the so-called secondary prophylaxis. It is focused on monitoring and diagnosing certain categories of diseases - screening for breast cancer, eye screening, etc. The goal is by conducting a specific medical screening, if necessary, to direct the person to the right medical specialist, to appoint specific tests and to determine the relevant treatment.

It is legally regulated in Ordinance No 8 of 3 November 2016 for preventive examinations and screening. Section III, Article 15 (1) of the Ordinance states that "screening is a prophylactic method for detecting the spread of a particular sign, symptom, or disease amongst groups of the healthy population." Screening can be performed if the following requirements are met:

1. screened disease is a major public and health problem;
2. there are validated means and methods of diagnosis and treatment in relation to the symptom / disease underlying the screening;
3. the disease can be detected in a clinically not manifested (latent) or early stage;
4. there is an established procedure for further diagnosis

and effective treatment of the persons under investigation;

5. the screening methods, tests and / or examinations used are easily applicable and safe for the population;

6. screening is cost-effective.

Medical screening is also available for women wishing to become pregnant and those pregnant in a particular gestational age. For example, we can indicate a prenatal biochemical screening (risk assessment study for a child with Down syndrome and some other congenital abnormalities of the fetus), biochemical serum screening (a study that is available to pregnant women to assess the risk of chromosomal abnormalities of the fetus - Down syndrome, Edvard syndrome, Patua syndrome, Turner syndrome, triplex etc.). Medical screening is generally applied to healthy individuals. As a result, it often appears that people are in an asymptomatic or very early clinical stage of a particular disease.<sup>11</sup>

## RESULTS

When talking about regulatory regulation in the healthcare sector, we should keep in mind the specificity of the sector's activity and the lack of a practical opportunity to regulate in detail all the private cases that are formed daily. The efforts made by the legislature to regulate all issues related to human health, diagnosis, treatment and access to medical care are indisputable. In recent years, however, there is often the impression in the public domain of the lack of relevant regulation on specific issues in the sector and lack of administrative control. This impression is incorrect, and the existence of several statutory and secondary legislation proves this (Constitution of the Republic of Bulgaria, Health Act, Health Insurance Act, Medical Institutions Act, Human Medicine Products Act, Human Organs, Tissue and Cells Transplantation Law, Blood, Blood Donation and Blood Transfusion Act, as well as a range of medical standards for specific subjects). The professional organizations of the doctors and dentists, who write the Principles on Good Medical Practice and the Code of Professional Ethics for doctors in Bulgaria, are also actively involved here. These acts of professional organizations aim to practically complement the existing regulatory framework. There is also a fair number of monitoring bodies looking after the quality of medical care (Executive Agency 'Medical Audit', which is currently being transformed into EA "Medical Surveillance"), its proper valuation, reporting and payment (NHIF), the conditions under which medical care is provided (RHI), health promotion (NCPHA), the competence of the persons who exercise it (BMA), the state health control of compliance with the requirements for protection of persons from the impact of ionizing radiation carried out by the NCRRP, etc.

### 1. Constitution of the Republic of Bulgaria.

Looking at issues relevant to health prevention and health prophylaxis, it should be noted that, in the first place, they are regulated indirectly by the provision of Art. 52 (3) of the Constitution of the Republic of Bulgaria which states

that “the state protects citizens’ health and promotes the development of sport and tourism”. From the cited normative text, the following conclusions can be drawn:

- through its specialized bodies - Regional Health Inspection and the National Center of Public Health and Analyses, the state guarantees and controls the existence of a safe and healthy living environment for the population.

- the state, in the face of the Ministry of Health and the Ministry of Youth and Sports, develops and conducts strategies targeted at specific populations to increase physical activity and improve physical and mental health.

## 2. Health Act.

Article 2 of the Health Act states that “The protection of citizens’ health as a state of complete physical, mental and social well-being is a national priority and is guaranteed by the state by applying the following principles:

1. equal treatment in the use of health services;
2. provision of accessible and quality health care with priority for children, pregnant women and mothers of children up to the age of one;
3. the priority of health promotion and integrated disease prophylaxis;
4. preventing and reducing the risk to the health of citizens due to the adverse impact of the factors of the living environment;
5. special health protection of children, pregnant women, mothers of children up to the age of one and persons with physical disabilities and mental disorders;
6. state participation in the financing of activities aimed at protecting the health of the citizens.

The cited provision is a natural extension of the constitutional principle laid down in Article 52 of the Constitution. In point three of the provision of Article 2 of the Health Act, a policy for the promotion of prevention and public health promotion is defined as a priority.

The state health control on the territory of the Republic of Bulgaria is legally defined in Article 12 of the Health Act and is exercised by the chief state health inspector, regional health inspectorates and the National Center for Radiobiology and Radiation Protection (NCRRP). Article 14 of the Health Act sets out the main powers of the chief health inspector, the most important of which are the activities of health promotion and integrated prophylaxis of diseases and prophylactic and anti-epidemic activities in case of disasters, accidents and catastrophes.

## 3. Ordinance No 8 of 3 November 2016 for preventive examinations and screening.

From a normative point of view, attention is paid to Ordinance No 8 of 3 November 2016 for preventive examinations and screening. It defines the conditions, the order and the financing for performing the preventive examinations and the screening as well as the list of the diseases, in which the screenings are performed. Article 2 of the Ordinance stipulates that preventive examinations and studies are aimed at early detection of diseases. Preventive examinations are performed by a doctor in outpatient medical and dental care establishments.

The ordinance explicitly states that preventive examinations, investigations and screenings are performed in accordance with medical standards and good medical practice. The length of the preventive examination and the screening review is determined by the medical practitioner according to the volume and scope of the necessary medical activities, including the follow-up on the results of the tests and consultations.

## DISCUSSION

The following optimization suggestions have emerged from the brief overview of the issues related to health promotion, prevention and medical screening:

1. The sub-legislative framework regulating the issues in question should be expanded. Establish clear and specific normative texts that define the arrangement and frequency of the preventive measures for the population. At present, such overhead processes are observed in the compulsory vaccinations of newborns and adolescents, for the existence of which the legislator has explicitly introduced a statutory requirement, in the absence thereof, an administrative penalty is imposed.

2. Practically it is necessary to conduct regular campaigns related to the promotion of medical screening. At present, such campaigns are rare and are usually costly. This makes them virtually inaccessible to most of the population. They are carried out mainly in particular settlements, which to a large extent limits the access to them.

3. Regarding the issue of health education, we should point out that it is missing in the curriculum at present. It is being relied primarily on the family culture and upbringing of adolescents. The relationship of partnership between the state and the individual family unit is broken in this sense. The lack of communication in this aspect gives a practical negative reflection in the adolescent health care culture, who will eventually become full members of society and create their own families.

4. The lack of correlation between the frequency of prophylactic campaigns conducted by competent health authorities and the needs of society increases the presence of collisions in general health education and reduces the incidence of individual responsibility for their own health. As a result, the healthcare system is increasingly finding higher levels of morbidity among the population and progressively rising healthcare spending over the last decade. Undoubtedly, urgent measures should be taken to immediately put an end to this vicious structure of the practice.

## CONCLUSIONS

Undoubtedly, the systematic study has resulted in several problems and regulatory gaps in the existing public health legislation. Despite the concentrated efforts of the Ministry of Health, the professional organizations and the leg-

islator, the Republic of Bulgaria lags tangibly in the formation, stimulation and financing of medical screening and prevention. The issue in question is partly present in the national health strategies that have been developed. The financial resources allocated to preventive activity are insignificant. A conceptual mistake is to limit this resource to the form of medical referrals. Such a health policy restricts the patient's access to consult a specialist when necessary in order to prevent serious and irreversible pathological disabilities in a timely manner.

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## Этические и правовые аспекты медицинского скрининга для ранней диагностики заболеваний. Превенция и профилактика

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**Введение:** Основные приоритеты проводимой политики в области здравоохранения в Республике Болгария непосредственно направлены на поддержание и улучшение здоровья населения, обеспечение равного доступа пациентов к современному и эффективному здравоохранению, быстроту и качество в соответствии с нормативными требованиями предлагаемых медицинских услуг. В этом смысле основное внимание в политике здравоохранения уделяется превенции и профилактике ранней диагностики заболеваний. Гораздо разумнее предупредить заболевание или контролировать его на ранней стадии, чем отложить лечение до тех пор, пока патологический процесс не разовьётся в тяжёлые или необратимые осложнения.

**Цель:** Целью данного систематического обзора является изучение эффективности существующих правовых актов, регулирующих реализацию общей политики здравоохранения в области укрепления здоровья и профилактики. Другой целью является выявление пробелов в законодательстве и внесение адекватных предложений по оптимизации.

**Материалы и методы:** Анализ этого систематического обзора основан на подробном обзоре существующей правовой базы (действующее и регулирующее законодательство, прецедентное право, европейская практика), которая относится к общественному здравоохранению. Статьи, которые сосредоточены непосредственно на медицинском обследовании и проблемах общественного здравоохранения с национальной и глобальной точки зрения изучаются.

**Результаты:** Обсуждаются два основных правовых акта, два положения и стратегии Всемирной организации здравоохранения. Представлены предложения по оптимизации контрольной деятельности административных органов в отрасли.

**Выводы:** На основе анализа сделаны предложения по оптимизации существующей правовой базы в сфере здравоохранения. Предложения основаны на результатах анализа мировых тенденций в методологии государственного финансирования медицинского скрининга для ранней диагностики заболеваний.

Рассматриваемая проблема является современной и поднимает вопросы права, моральных, этических и деонтологических принципов, которым придерживается медицинская профессия, а также политики здравоохранения, которой придерживается Министерство здравоохранения в этом аспекте.