

LEGAL ASPECTS OF CANCER DISEASES PROPHYLACTICS: PATIENTS RIGHTS CONTEXT

PRAWNE ASPEKTY PROFILAKTYKI CHOROÓB NOWOTWOROWYCH W KONTEKŚCIE PRAW PACJENTA

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ABSTRACT

Introduction: In accordance with Resolution on Cancer Control WHA58.22 Cancer prevention and control The Fifty-eighth World Health Assembly it is obvious technology for diagnosis and treatment of cancer is mature, and that many cases of cancer may be cured, especially if detected earlier Some key points on concept of legal regulation of abovementioned sphere is a base of this study. However, the problems of using an effective mechanism for protecting the rights of patients in certain types of disease, in particular cancer patients, by providing early diagnosis, are not fully developed by medical law specialists.

The aim of the article is to determine the means of ensuring the right to health and life of cancer patients in particular through early diagnosis.

Material and Methods: This study is based on regulation acts, World health report (2013), The Fifty-eighth World Health Assembly, WHA58.22 Cancer prevention and control, Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights, European Convention for the Protection of Human Rights and Fundamental Freedoms, Charter of Fundamental Rights of the European Union, research papers and views of progressive-minded people in this sphere. Article is grounded on dialectical, comparative, analytic, synthetic and comprehensive research methods.

Review: Most countries have declared a compliance of their national legislation with international standards regarding the right to life and health. The analysis of the abovementioned international acts in context of protection of the rights of patients with cancer leads to the conclusion that countries that have undertaken international legal obligations to protect the right to life are required to take the necessary measures to ensure the effective treatment of cancer patients. Taking into account that the lack of such treatment due to the specificity of the disease entails the death of the patient, the state inaction in this area should be regarded as a violation of a human right for life. Absence of state's policy in terms of early detection of cancer brings a huge problem of human rights violation and providing the standards of fundamentally different approach of the European Union countries could become a great solution.

Conclusions: Individual states do not pay sufficient attention to the need of effective public health policy. In today's world, there are objective prerequisites for changing the system of protection of patients' rights and, consequently, for changing views on health protection in general, especially in the part of functioning of diagnostic procedures system. Formation of a state policy on ensuring the rights of citizens to health and life, taking into account the various consequences of such a policy, cannot be narrowed down only to the proclamation of such rights, but also requires planning and development of relevant state programs.

Failure by the state to provide the proper organization of health care through the establishment of early diagnosis for cancer patients, considering wide incidence and mortal danger of cancer in case of late diagnosis, should be considered as a violation of human rights. It also does not conform to ECHR practice in terms of provisions of Articles 2, 3 and 8 of European Convention.

KEY WORDS: cancer disease prophylactic, early cancer diagnosis, patients' rights

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INTRODUCTION

In accordance to main messages from World health report 2013: Research for universal health coverage: «Universal health coverage means that everyone has access to quality health services that they need without risking financial hardship from paying for them. This requires a strong, efficient, well-run health system; access to essential medicines and technologies; and sufficient, motivated health workers. The challenge for most countries is how to expand health services to meet growing needs with limited resources» [1]. Meanwhile, the analysis of the situation in many countries of the world including Ukraine shows that underfunding

of the public health system in many cases leads to untimely prevention of certain types of diseases, in particular for cancer patients. In countries that do not take the necessary measures to increase the scope and improve the quality of early diagnosis of cancer the main part of mortality from this disease is due to the untimely detection of cancer symptoms.

In accordance with Resolution on Cancer Control WHA58.22 Cancer prevention and control The Fifty-eighth World Health Assembly it is obvious technology for diagnosis and treatment of cancer is mature, and that many cases of cancer may be cured, especially if detected earlier

[2]. It should be noticed that in this context it is expected, that annual cancer cases will rise from 14 million in 2012 to 22 within the next two decades [3].

The majority of people, who are diagnosed with cancer, live in low- and middle-income countries (LMICs). In 2015, 8.8 million people died from cancer, representing one to six deaths globally (2). The number of deaths due to cancer in LMICs exceeds those due to HIV/AIDS, tuberculosis and malaria combined. Approximately two thirds of global cancer deaths are in less developed countries, where mortality rates are higher due to lack of detection and less accessible treatment [4].

For example, in Ukraine according to the National Cancer Registry there were 131,504 cases of cancer and 65,629 cases of death from cancer in 2016. Therefore, it can be stated that nearly 360 Ukrainians get ill, and 179 people die due to cancer every day, every hour 15 cases of cancer are diagnosed and 7 people die from cancer in Ukraine. [5]

An analysis of the current situation in Ukraine makes it plausible that the lack of an effective early cancer prevention system due to the underfunding of the health care system and the lack of effective management in this area could be considered a violation of patients' rights. The right to health is violated by restriction of the right to early diagnosis in order to detect cancer in the early stages. Moreover, such restriction in many cases leads to violation of the right to life, taking into account the specificity of disease progress and the possibility of its treatment.

It should be noted that scholars have paid enough attention to the protection of patients' rights, in particular, the human rights framework in cancer care [6], the justiciability of the right to health care through the prism of a courts practice [7], the human rights to health[8], the right to access health care, the right to information, and the right to remedy [9], women's health and human rights [10] research the status of the implementation of the Act on the Protection of Patients' Rights form 2004 in the Republic of Croatia [11], Attention is paid to the importance of transplantation as a method of treatment and saving human lives [12], how the legal regime of intellectual property affects the availability of medicines for people [13], develop special rules for the application of the national mark of conformity for medical device software [14], the legal regulation of software which is used for medical purpose [15], detailed examination of the nature of the prohibition of the medicines distance selling [16], etc. However, the problems of using an effective mechanism for protecting the rights of patients in certain types of disease, in particular cancer patients, by providing early diagnosis, are not fully developed by medical law specialists.

THE AIM

The purpose of the article is to determine the means of ensuring the right to health and life of cancer patients in particular through early diagnosis.

MATERIAL AND METHODS

This study is based on regulation acts, World health report (2013) [1], The Fifty-eighth World Health Assembly, WHA58.22 Cancer prevention and control [2], Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights, European Convention for the Protection of Human Rights and Fundamental Freedoms, Charter of Fundamental Rights of the European Union, research papers and views of progressive-minded people in this sphere. Article is grounded on dialectical, comparative, analytic, synthetic and comprehensive research methods.

REVIEW AND DISCUSSION

It should be noted that most countries have declared a compliance of their national legislation with international standards regarding the right to life and health. Such standards are constituted in Universal Declaration of Human Rights – article 3, which regulates that «Everyone has the right to life...» and article 25 states that «Everyone has the right to a standard of living adequate for the health». Among the others, there are International Covenant on Civil and Political Rights, Optional Protocol to the above-mentioned Covenant (Article 3), International Covenant on Economic, Social and Cultural Rights (Article 11), The Convention for the Protection of Human Rights and Fundamental Freedoms (Article 2), European Social Charter (Article 12), Charter of Fundamental Rights of the European Union (Article 2). Additional and broader concept is described in soft-law act - European Charter of Patients' Rights, that declares reasonableness of positive obligations of States to protect and promote patients' rights.

The analysis of the abovementioned international acts in context of protection of the rights of patients with cancer leads to the conclusion that countries that have undertaken international legal obligations to protect the right to life are required to take the necessary measures to ensure the effective treatment of cancer patients. Taking into account that the lack of such treatment due to the specificity of the disease entails the death of the patient, the state inaction in this area should be regarded as a violation of a human right for life.

Public authorities in healthcare are trying to avoid fulfilling their international legal obligations referring to financial difficulties by leaving cancer patients on their own in terms of payment for medical treatment. This situation applies not only to adults but also to children with cancer whose obligation of material support for medical treatment rests with their parents. For example, the Accreditation Commission of the Ministry of Health of Ukraine recommended the «Okhmatdit» (Specialized Hospital for the treatment of cancer patients), to introduce paid medical services [17]. In our opinion, there is an obvious violation of requirements of the aforementioned documents concerning the right to life and a sufficient standard of living.

The peculiarities of the course of oncological diseases and the possibility of their effective treatment proving

the existence of regularities: the earlier the disease will be detected, the more effective the treatment can be and the lower the risk of death for the patient. In view of this, the necessity of providing by the state the possibility of an effective and accessible early diagnosis of oncological disorders with the use of modern scientific approaches becomes extremely important.

In order to this Resolution on Cancer Control WHA58.22 World Health Assembly proposed to improve access to appropriate technologies with support from WHO for the diagnosis and treatment of cancer in order to promote its early diagnosis and treatment, especially in developing countries [2]. Urges Member States: (4) to encourage and to frame policies for strengthening and maintaining technical equipment for diagnosis and treatment of cancer in hospitals providing oncology and other relevant services; (11) to assess periodically the performance of cancer prevention and control programmes, allowing countries to improve the effectiveness and efficiency of their programmes; (13). Annex to the report on the prevention and control of cancer recommended to National cancer control Programmers to include «cancers amenable to early detection and treatment (such as oral, cervical, breast and prostate cancers): to reduce late presentation and ensure appropriate treatment, in order to increase survival, reduce mortality and improve quality of life» [2].

However, from the point of view of Ukraine's healthcare operators in the case of a diagnosis of cancer the answer for "to be or not to be?" question, as cynically as it may sound, depends on money [18]. Although it should be noted that in some countries, in particular, China, India and Russia due to lack of early diagnosis of cancer detection cancer diseases is revealing too late (at 3rd or even 4th stages), or patients die without a cancer diagnosis at all. Such trend leads to a reduction in statistical data numbers on the incidence of cancer (the number of diagnoses) compared to developed countries, where the proportion of detected patients is significantly higher. With appropriate level of medicine the survival rate and life expectancy of patients with early stages of cancer is very high therefore the statistics of recorded number of cancer patients in developed countries is higher compared to the underdeveloped ones [19].

Thus, in Ukraine among the 200 thousand of people with cancer diseases, about 80 thousand people die in the first year after diagnosis and this means that the disease is detected too late – at the third and fourth stages. Treatment requires high financial and psychological costs for the patient and his family and it is difficult to guarantee the treatment success in such cases. The early stages of cancer disease are treatable but timely diagnosis is ultimately needed [20]. Meanwhile, statistics adapted from the American Cancer Society's publication, Cancer Facts & Figures 2016, and the National Cancer Institute Surveillance Epidemiology and End Results (SEER) database confirm that first: «If doctors detect colorectal cancer early, the 5-year relative survival rate is 90%» [21]; second: «The 5-year relative survival rate for early-stage cervical cancer is 92%. This means that 92 out of every 100 women with early-stage

cervical cancer will be alive 5 years after diagnosis» [21].

That is, despite the existence of legal grounds for ensuring the right to health and life at the level stated in international documents, the authorities of some countries (Ukraine in particular) do not provide all necessary measures for the early detection of the disease which in most cases leads to the death of patients. However, among principles of Constitution of WHO it can be found that «Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures» [22].

The disease has brought into being an entire industry of research organizations, charitable agencies, commercial ventures, and advocacy groups. Every new statistic is trumpeted in the media, and every encouraging research finding, no matter how tenuous, is held up as a potential breakthrough [23]. However, this does not sufficiently protect the rights of cancer patients to early diagnosis. In some countries, despite the appropriate recommendations of World Health Organization at the regulatory level national law does not adequately protect cancer patients.

Russian Federation has lapsed and has not been renewed since 2014 the national Cancer Program due to the fact that over the five years of the program cancer mortality fell by only 1% [19].

The National Program on Cancer Control for the period up to 2016, which was established in Ukraine by the Law of December 23, 2009, was also not prolonged for the next term without any official explanations. The State Program "Child Oncology" for 2006-2010, which was approved by the Cabinet of Ministers of Ukraine dated July 19, 2006, was also not prolonged without any explanation. However, Ukraine, along with Russia demonstrates the worst results in terms of ensuring the right to life and health, particularly for cancer patients.

Meanwhile, the Program, among the ways of solving problems established the renewal of oncological preventive surveys and dispensary surveillance of patients with precancerous pathology in ambulatory and polyclinic institutions, ensuring the appropriate interaction of health care institutions and implementing a systematic approach and modern principles of the organization of diagnosis, treatment and rehabilitation of patients with malignant neoplasms, rising the level of morphological and molecular genetic diagnostics to European standards, as well as equipping health facilities with the necessary equipment for conducting scientific research in the field of oncology on the basis of evidence-based medicine. However, early diagnosis with the use of the necessary equipment based on European standards have not yet been implemented.

As a base of study, we will take Poltava region and appropriate statistic data. As of 01.01.2017, there are 38579 patients with cancer at the dispensary inspection. The mortality rate from malignant neoplasms only in 2016 amounted to 190.5 per 100 thousand persons; the five-year survival rate is 60%. Special attention in terms of early diagnosis is needed for one of the most common among women type of cancer – cervical cancer.

The Resolution on Cancer Control WHA58.22 points out that among all cancer sites cervical cancer, causing 11% of all cancer deaths in women in developing countries, has one of the greatest potential for early detection and cure, that cost-effective interventions for early detection are available and not yet widely used, and that the control of cervical cancer will contribute to the attainment of international development goals and targets related to reproductive health [2].

According to the Department of statistics, there are 1.43 million of inhabitants in Poltava region as of the end of 2016. Among them on the basis of data from the Department of Health, at the dispensary register of the oncology clinic were 2086 women as of 01.01.2017, 1455 (69.8%) of them stayed registered for more than 5 years. Every year in the Poltava region cervical cancer are diagnosed for about 180 women. In 2016, 175 women were diagnosed with cervical cancer in for the first time including women in abnormal stages: the third stage - 20; IV stage - 8, among them 11 were 20 to 50 aging category (39%). From 175 cases of cervical cancer 80 patients were aged from 20 to 50 years (44.9%).

The information above is indicative in the context of letter of the Chief medical officer of the Poltava Regional Clinical Oncology Center May 23, 2017 No. 413 to the Director of the Department of Poltava Regional State Administration with request not to purchase fluid cytology equipment for oncology dispensary. For reference, equipment for liquid cytology serves to establish a precancerous condition, since precancerous condition is much easier to treat than one on the disease stage. In order to detect such changes it is necessary to conduct a cytological screening (testing).

According to that letter, the Chief medical officer believes in connection with the fact that we quote below that "... if the needs of cytological screening is 500 thousand women in the Poltava region and the cost is UAH 250 per one test, so then, if at least 10% of women are tested, it will require UAH 11'577'975 per one year". Basing on these calculations, the administration of the Poltava Regional Clinical Oncology Center has come up with a proposal to change the procurement subject from the equipment for liquid cytology to other equipment that is necessary for operational intervention. It is used not for the early detection of precancerous conditions, of course. Furthermore, there was added a separate analysis of the costs of conventional treatment for patients with the above diagnosis.

Among the patients, there were 209 people in 2016 who received special treatment for this diagnosis, 131 of whom were registered for the first time. Among the first-time registered 23 patients received surgical treatment only, 30 people - chemotherapy only, 25 people - chemo-ray therapy and 40 patients - combined treatment. Thus, the surgical method of treatment was received by 63 patients, and chemotherapy - by 55 patients. Based on the statistics, the calculation of the cost of surgical treatment for 63 patients was made: $63 \times 1'048.43 = \text{UAH } 66'051.09$. Cost of carrying out of chemotherapy courses for this localization per 1 year: $55 \times 57'788 = \text{UAH } 3'178'340$

As a result, equipment for the early detection of a possible disease has not been purchased however, it was planned to purchase equipment for surgical intervention in the treatment of cancer patients, including a significant number of those to whom the disease was not detected in the early stages. The refusal of using the early diagnosis in such cases must be considered as a violation of the rights of patients granted by the national legislation of Ukraine, in particular the Constitution of Ukraine, the Civil Code and the Fundamentals of Health Protection Law. However, national legislation of Ukraine, unlike the legislation of the European Union, does not explicitly specify the patients' rights to use innovative treatment technologies.

A fundamentally different approach has been applied in the countries of the European Union. For instance, European Charter of Patients' Rights regulates: «10-Right to Innovation Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations. The health services have the duty to promote and sustain research in the biomedical field, paying particular attention to rare diseases. Research results must be adequately disseminated». Additionally, European Charter of Patients' Rights despite the fact that it is a soft-law act, constitutes that: «Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs. The health services must guarantee, to this end, flexible programmes, oriented as much as possible to the individual, making sure that the criteria of economic sustainability does not prevail over the right to health care».

The fact of patients' rights violation in cases where the state does not properly manage healthcare by not using the innovative ways of early diagnosis of oncological diseases available should be considered as a violation of the right to life. This circumstance is also drawn by experts of the FXB Center for Health and Human Rights at Harvard University in the "Health and Human Rights Resource Guide", prepared by the initiative of Open Society Foundations. For example, the authors of Chapter 1 of this paper - "Patient Care and Human Rights" - Angela Duger, Jennifer Leaning, Sarah Dougherty, Judy Overall, Tamar Ezer - in Table 5: "Patient Care and the Right to Life" define as a violation of the right to life such an organization of the state health protection, when "Health services do not include preventive screening for many types of cancer. As a result, patients learn they have cancer when it is already too late for effective treatment". [24, p. 1.23]

Such a conclusion provide grounds for considering such actions of the state in the context of violations of human rights declared by European Convention for the Protection of Human Rights and Fundamental Freedoms [25].

The convention, as emphasized in the decisions of the European Court of Human Rights (ECHR), does not guarantee the adequate protection of social human rights, including a right to free medical care (See: *Valentina Penti-acjdf and Others v Moldova*, application no 14462/03 [26]; *Zdzisław Nitecki v. Poland*, application no. 65653/01 [27];

R.R. v. Poland, application no 27617/04 [28]. “While it is clearly desirable that everyone should have access to a full range of medical treatment, including life-saving medical procedures and drugs, the lack of resources means that there are, unfortunately, in the Contracting States many individuals who do not enjoy them, especially in cases of permanent and expensive treatment”. [26]

However, in cases where the lack of access to proper treatment due to inadequate management of healthcare, entails violations of other human rights guaranteed by the Convention, ECHR interpreted such actions as a violation of human rights by the state. This is, in particular, a violation of Right to life (article 2), Prohibition of torture (article 3) and Right to respect for private and family life (article 8).

For instance, ECHR in the decision *William and Anita Powell v. the United Kingdom*, application no. 45305/99 concludes, that “admittedly the first sentence of Article 2 enjoins the State not only to refrain from the intentional and unlawful taking of life, but also to take appropriate steps to safeguard the lives of those within its jurisdiction... The Court accepts that it cannot be excluded that the acts and omissions of the authorities in the field of health care policy may in certain circumstances engage their responsibility under the positive limb of Article 2.” [29] The reference to the above provision is also contained in the decision of ECHR *Cyprus v. Turkey*, application no. 25781/94, 10/05/2001 [30]. In this decision, “The Court observes that an issue may arise under Article 2 of the Convention where it is shown that the authorities of a Contracting State put an individual’s life at risk through the denial of health care which they have undertaken to make available to the population generally”.

In a decision of the case *Mehmet Şentürk and Bekir Şentürk v. Turkey*, application no13423/09 [29] the applicants applied to ECHR with a complaint that his wife and mother, Mrs Menekşe Şentürk, who was on 3-rd to 4 months of pregnancy, did not receive medical care of an appropriate quality. When the hospital discovered that the child had died and there was a need for urgent surgery, the hospital was refused hospitalization because the applicant could not pay for it. She died when she was transported to the other hospital in a car without any medical personnel. ECHR, referring to the decision *William and Anita Powell v. the United Kingdom* [29] concludes, that: “That being so, the Court reiterates that the positive obligations imposed on the State by Article 2 of the Convention imply that a regulatory structure be set up, requiring that hospitals, be they private or public, take appropriate steps to ensure that patients’ lives are protected”. Based on those principals, ECHR in further decisions where the facts of the death of a patient (patients) in hospitals due to improper provision of medical care were considered, in particular in the case *Valeriy Fuklev v Ukraine* [31] and *Elena Cojocaru v Romania* [32] states the same. Thus, in cases where the proper system of organization of health care is directly related to ensuring the human right to life, the ECHR considers the state’s inadequate activities to ensure such a right as a violation of Article 2 of the Convention.

Violation of patients’ rights through lack of access to prenatal genetic tests resulting in inability to have an abortion on grounds of foetal abnormality recognized by the ECHR

as a violation of prohibition of inhuman or degrading (article 3) and Right to respect for private and family life (article 8). Decision on *R.R. v. Poland*, application no. 27617/04 [28] where the court notes that: «There was a wide consensus that in the administration of health-care systems, Contracting Parties were obligated positively to ensure reasonable availability of diagnostic services to enable patients to have the information necessary to make medical decisions significant for their health and family well-being.» (п. 137). Next, p. 139 of the Decision highlights, that: «Doctors can exploit their professional authority to treat female patients according to their own beliefs and sex-based stereotypes, rather than according to the actual needs of such patients. When patients were treated in ways unrelated to their own medical needs, and to their own priorities and aspirations, but rather as a means to advance doctors’ own ends, there was a form of degrading treatment». [28].

The judgment of the ECHR, in our opinion, could be applied as a precedent for the legal assessment of the violation of patients’ rights to health by eliminating the possibility of early diagnosis of cancer in general and cervical cancer in particular. Failure by the state to undertake appropriate measures to ensure proper health care in this area, taking into account the widespread and deadly risk of cancer should be considered as a violation of Articles 2, 3 and 8 of the Convention.

CONCLUSIONS

The foregoing suggests that individual states do not pay sufficient attention to the need of effective public health policy. In today’s world, there are objective prerequisites for changing the system of protection of patients’ rights and, consequently, for changing views on health protection in general, especially in the part of functioning of diagnostic procedures system.

However, in order to have an effective regulative impact on the content, the nature and intensity of activities in the field of health care there must be some kind of preliminary practice of state authorities in: studying the state and dynamics of these public relations; their legal assessment; prognostication of consequences from neglecting of processes in the field of providing the right to health; elucidation of resource and instrumental possibilities of the state concerning effective influence on protection of citizens’ rights to health and life. Meanwhile, it must be admitted that the formation of a state policy on ensuring the rights of citizens to health and life, taking into account the various consequences of such a policy, cannot be narrowed down only to the proclamation of such rights, but also requires planning and development of relevant state programs.

Analyzing the content of the declarative documents on the right to health and life, which is recognized as a typical form of state policy statement, it should be noted that their provisions should become a key source of law-making activity of the state in the relevant field of legislative regulation, and in the broader sense - the source of the organization of legal impact on health care relations. Failure by the state to provide the proper organization of health care through the establish-

ment of early diagnosis for cancer patients, considering wide incidence and mortal danger of cancer in case of late diagnosis, should be considered as a violation of human rights. The analysis of the practice of the ECHR makes it possible to state that such inaction of the state is an obvious violation of Right to life (article 2), Prohibition of tortures (article 3) and Right to respect for private and family life (article 8).

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