Revista Bioética
Print version ISSN 1983-8042 | On-line version ISSN 1983-8034

Rev. Bioét. vol.30 no.4 Brasília Oct./Dec. 2022

Oncogenetics and Status of Cancer Patients: bioethical and legal foundations

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Abstract

This paper analyzes bioethical and legal foundations that contributed to establish the current normative discipline of access to oncogenetic resources from the perspective of the Statute of the Person with Cancer. It sought to evaluate the current state of legislation that upholds the rights of patients regarding oncological demands, considering the fundamental rights to life and health. The central premise was to clarify the status of oncology-related resources, which includes precision medicine and oncogenetics, to subsequently address limitations on their access within the Unified Health System or supplementary health. This is a theoretical research based on the survey of national and international references, specialized publications, and current Brazilian legislation.

Keywords: Right to health. Medical oncology. Bioethics.

Resumo

Oncogenética e Estatuto da Pessoa com Câncer: fundamentos bioético-jurídicos

Este artigo visa analisar fundamentos da bioética e do direito que contribuíram para estabelecer a disciplina normativa atual do acesso aos recursos da oncogenética sob a perspectiva do Estatuto da Pessoa com Câncer. Buscou-se avaliar o estado atual da legislação que apregoa os direitos dos pacientes quanto às demandas oncológicas, tendo em vista a fundamentalidade dos direitos à vida e à saúde. A premissa central foi esclarecer a situação dos recursos relacionados à oncologia, o que inclui a medicina de precisão e a oncogenética, para, posteriormente, abordar as limitações sobre o seu acesso, no âmbito do Sistema Único de Saúde ou da saúde suplementar. A pesquisa tem natureza teórica, consistindo em levantamento de referências nacionais e estrangeiras, em publicações especializadas, bem como na legislação brasileira vigente.

Palavras-chave: Direito à saúde. Oncologia. Bioética.

Resumen

Oncogenética y Estatuto de la Persona con Cáncer: fundamentos bioético-legales

Este artículo tiene como objetivo analizar los fundamentos de la bioética y del derecho que contribuyeron a establecer la disciplina normativa vigente del acceso a los recursos oncogenéticos desde la perspectiva del Estatuto de la Persona con Cáncer. Su objetivo es evaluar el estado actual de la legislación que trata los derechos de los pacientes frente a las demandas oncológicas, considerando los derechos a la vida y a la salud como fundamentales. La premisa central fue esclarecer la situación de los recursos relacionados con la oncología, que incluye la medicina de precisión y la oncogenética, para posteriormente abordar las limitaciones en su acceso en el ámbito del Sistema Único de Salud o de la salud complementaria. El estudio de naturaleza teórica realizó una búsqueda de referencias nacionales y extranjeras de publicaciones especializadas, así como en la legislación brasileña vigente.

Palabras clave: Derecho a la salud. Oncología médica. Bioética.

The authors declare no conflict of interest.

The dynamic nature of medicine enables significant advances in scientific discoveries, enabling it to incorporate new diagnostic and therapeutic protocols into the treatment of serious diseases such as cancer. Such possibilities, however, require the support of legal specialists, as well as reflection on their relevant bioethical aspects.

The incidence of cancer is very significant, as demonstrated by the statistics produced by competent bodies in various parts of the world. Guaranteeing the rights of cancer patients is a global interest and they must be based on assumptions of adequacy and speed. The protection of these rights is accompanied by reflections based on the principle of bioethics included in theoretical frameworks and international documents in addition to being reflected in the content provided for in domestic legislation.

This research proposes to discuss the use of genetic tests in patients diagnosed with cancer or patients without a diagnosis but with an expressive family history of cancer since they represent prophylactic and therapeutic possibilities which are relevant to oncology. The parallel incorporation of resources provided by medicine requires an appropriate legislative policy, with less bureaucracy and unrestricted to economic foundations.

Recent laws, no. 14,238/2021 [1] and no. 14,307/2022 [2], represent new and important perspectives since they rethink (albeit in part) a restrictive stance regarding access to new drugs and treatments in the oncology field. They should also support the promotion of precision medicine through knowledge of oncogenetics.

The purpose of this study is to investigate the extent to which the regulatory content of the Statute of the Person with Cancer [1] corroborates the need to promote equal access to genetic tests and diagnoses in contexts in which there is justifiable medical evaluation. We therefore seek to establish the relation between predictive medicine - which sometimes requires the use of medications and surgeries for prophylactic purposes - with the rights clearly set out in the statute.

This is a bibliographic survey which is consolidated by references in chapters and scientific articles from the medical and legal fields published by Brazilian and foreign authors, in addition to laws, resolutions, and regulatory acts in a broad sense. A deductive method was used, identifying the grounds that justify revising the regulatory constraints regarding the incorporation of resources related to the predictive sphere to assess their adequacy, measured by deduction, considering the actual implementation of the fundamental right to health.

Precision medicine and oncogenetics

Currently, one can see that cancer (no longer conceived as a single disease) shows a constellation of diseases that can be divided into several subtypes according to different factors, including genetics [3]. The discovery of this factorial multiplicity, which includes the importance of genetic information, encouraged the search for personalized treatments and the best prediction of therapeutic responses, leading to the emergence of the term "precision medicine" in the scientific field [3].

Precision medicine focuses on the individualized reality of the patient and shows an emerging approach, with a proposal focused on personalizing diagnosis/treatment and the possibility of preventing diseases, considering factors such as genetics, environment, and lifestyle [4]. Oncogenetics lies within precision medicine, a field of oncology that uses genetic information from patients or tumors as diagnostic, prognostic, and predictive biomarkers.

In clinical practice, this information is acquired from two types of genetic tests [5]: the first is performed on the tumor and serves to aid diagnosis or determine a treatment based on tumor mutations; the second is performed on normal (non-cancerous) cells to ascertain individuals' genetic characteristics and analyze whether they were born with any mutation in their DNA which increases their predisposition to cancer. These tests can also investigate the influence of genotype on drug metabolism profile, in the field known as pharmacogenetics [5].

Understanding the origin of cancer requires understanding the mutations that altered individuals' DNA sequence. *Somatic mutations are only found in tumor cells and accumulate due to the damage cells suffered during the carcinogenesis process and are therefore related to external factors, such as exposure to carcinogens and lifestyle habits* [6]. These somatic mutations are not transmittable in a hereditary fashion.

Germline mutations are alterations that originate in the sperm or egg and are therefore genetically transmittable. All diploid cells in the body have an *original germline mutation, so any examined cell will contain DNA mutations which can be investigated by genetic sequencing of the genes involved in the hereditary predisposition to cancer* [6].

Somatic mutations are responsible for about 90% of cancer cases, referred to as sporadic mainly because they are associated with external risk factors, such as lifestyle habits (smoking, alcohol consumption, etc.) and environmental exposure (ultraviolet radiation, ionizing radiation, etc.). Genetic or hereditary cancer, on the other hand, presupposes germline mutations, which occur in approximately 10% of cancer cases [7].

The diagnosis of cancer at an earlier age than usual and the identification of numerous cases of the same cancer in close relatives suggest a genetic predisposition to cancer. Individuals in this situation may derive significant benefits from counseling and genetic testing in view of personalized cancer screening and prevention protocols [8].

To assess predisposition, one should construct a genogram (a graphic representation capable of detailing family history), which must be included in individuals' medical records. Its detailed evaluation makes it possible to identify whether there are reasons to request genetic testing [5]. In the case of patients who have already been diagnosed with cancer, the tests enable the *appropriate alteration of treatment strategies. Likewise, the fact one can identify high-risk patients before the disease occurs implies the possibility of implementing strategies to reduce this chance in a very significant way* [9].

Access to genetic tests is still incipient since only such tests can identify individuals who should undergo personalized and more effective surveillance and cancer risk reduction strategies [10]. Tumor tests are widely-used instruments to improve diagnosis and the choice of therapy. Through them, several tumors that previously lacked effective care can now be treated with target molecular therapy based on the discovery of tumor mutations [11].

Among the goals of precision medicine lies the *detailed knowledge of patients' molecular profile and of their tumor will allow individualized therapies to improve results and reduce toxicity. Thus, accessing information on prognostic and predictive germline mutations, in addition to information about their drug metabolism profile (pharmacogenetic biomarkers), can individualize clinical management, sometimes defining the most appropriate drug, sometimes electing the best therapeutic dose* [12].

Despite the difficulty in carrying out complex genetic tests in precision oncology in countries such as Brazil, oncogenetics is established as an important tool for achieving individuals' right to health. Genetic tests have different characteristics and purposes: one must understand them to justify the expansion of its coverage, whether through supplementary health care or through the Unified Health System (SUS). In supplementary health, tumor tests may be requested by any medical professional, regardless of their specialty [13].

Regarding requests for germline genetic tests, the recently amended regulations of the National Health Agency (ANS) prevented access to these tests [14]. The criteria for justifying their coverage in the field of supplementary health are still restrictive and must be improved, considering that the situations that justify their need involve people who are yet to have cancer but belong to high-risk families [10].

Access to counseling and genetic testing at SUS is more difficult, even considering the incipient number of referral centers with specialized professionals. There are few equipped laboratories and trained people to perform and interpret such tests [10].

Precision medicine faces important ethical challenges, such as those related to the process of

obtaining informed consent, intimacy and privacy regarding genetic information, discrimination based on the diagnosis of hereditary predisposition to diseases, and the definition of clinical management in the face of inconclusive genetic findings [4].

The management of predictive information is directly related to the necessary guarantee of care, proclaimed by bioethical principles and now provided for by specific legislation. The Statute of the Person with Cancer [1] includes provisions in its framework that reaffirm the relevance of prevention and early diagnosis of the disease.

Statute of the Person with Cancer

Bioethical-legal reflections

Health is a fundamental right regarding its dynamism and progress as it is directly related to the evolution of science and the possibilities it develops, often transforming experimental knowledge into a consolidated therapeutic protocol. The context that associates the current conformation of the right to health with scientific progress must always be guided by ethical considerations and legality.

The pragmatism of scientific development requires, as a basis of its legitimacy, the idea of responsibility as a kind of guiding principle for overcoming risks based on respect for human beings in their evident condition of vulnerability [15]. Thus, scientific findings and their results must be weighed based on the benefit derived from a decision or conduct [16].

Prediction and precision are central to the current dimension of individuals' right to health. The possibility of anticipating the manifestation of a disease, such as neoplasms, transforms the classic notion of health—traditionally linked to the interventional sphere of healing, i.e., after the disease has begun. *Incorporating the predictive dimension of the right to health is therefore a regulatory mission since it is only through regulation that one can access it* [17].

Once the purpose of oncogenetics as one of the faces of precision medicine has been clarified, one must relate it to the pragmatic health bias, that is, to the means to implement the content provided for in the recently approved Statute of the People with Cancer [1]. Before that, however, the bioethical and legal foundations that underpinned the construction of these regulations are identified.

Chapter II of Law 14,238/2021 [1] dealt with the principles and teleological foundations that justified the construction of specific legislation [1]. This law is influenced by principles set out in the Federal Constitution and in international documents in line with objectives based on the protection of human rights and the existing internal system for the protection of fundamental rights [1].

There are many principles and objectives determined by law; this research highlights those directly related to the perspective of oncogenetics.

Article 2 of the Statute defines, among its essential principles, respect for human dignity, equality, non-discrimination, and individual autonomy; universal and equitable access to appropriate treatment; early diagnosis; encouragement of prevention; clear and reliable information about the disease and its treatment; provision of systemic treatment based on guidelines previously established by competent bodies; and expansion of the care network and its infrastructure [1]. In Article 3, the following essential objectives stand out:

- To promote the adequate mechanisms for the early diagnosis of the disease;
- To ensure adequate treatment, in accordance with laws already in force;
- To promote the prevention of the disease as well as the instruments to enable the National Policy for the Prevention and Control of Cancer in the Health Care Network for People with Chronic Diseases within the SUS scope;
- To encourage the creation and strengthening of public policies to prevent and fight cancer;
- To promote coordination between countries, bodies, and entities in favor of practices in the prevention and treatment of the disease;
- To promote the training, qualification, and specialization of people involved in cancer prevention and treatment process;
- To maintain the commitment to reduce the incidence of the disease through preventive actions;
- To encourage the creation, maintenance, and use of special prevention funds; and
- To prioritize prevention and early diagnosis [1].

Thus, the main role of the ideal of prevention is evident, especially as it relates to the extensive dimension of the concept of health, which encompasses the predictive sphere capable of anticipating care so that the disease does not take root, or to identify adequately individualized therapies.

Oncogenetics is a segment of medicine that contributes to the promotion of this predictive and precise dimension of the right to health, seeking prevention as its first approach. The principles of the legal text, as well as a significant part of its objectives, are also based on the promotion of a preventive conduct [1].

Legislation is related to the epistemological basis of principalist bioethics [16] insofar as it seeks to promote the principle of justice through fair access to health and, due to the role of charity, when it provides for a series of guarantees and prerogatives for cancer patients.

The rights recognized to cancer patients are also based on international documents on bioethics and human rights which express significant concern with the condition of human vulnerability and seek to promote well-being, health, and the right to life.

Oncogenetic relationship

Precision medicine becomes part of the essential tools for the effective guarantee of the right to health, becoming a new paradigm of medical science, as it sometimes enables the anticipation of the disease and the way in which it will manifest itself [18]. Oncogenetics, as explained earlier, is one of the expressions of this precision and directly relates to the assumptions contemplated by the Statute of the People with Cancer [1] since it enables therapeutic choices that can make a big difference.

Here, two points should be highlighted to establish the relation between oncogenetics and recently approved legislation: 1) the identification of oncogenetic information without undermining the foundations of ethics and legality and 2) the need to guarantee access to available resources based on the predictive and current dimension of the right to health.

The time lapse between the beginning of the Human Genome Project and the construction of recent Brazilian legislation in favor of the rights of cancer patients is evident. However, both must be united by the same challenge: the search for the ethical and legal conformation of conducts that accesses and interprets genetic information, that is, care with the interpretation and use of identified information. One should be reminded that the predictive capacity of tests does not exclude the fact that the information obtained from DNA has a statistical nature [19].

Brazil has no specific legislation addressing the implications of accessing genetic information. It only has sparse, partially explained regulatory provisions given the significant complexity of the subject. In the United States, for example, genetic non-discrimination is governed by a specific regulatory act which defines the various situations in which genetic information may be requested, accessed, or integrated into contractual relations, such as insurances, employment, provision of health services, among others [20].

In the Brazilian legal system, the right to genetic non-discrimination is derived from the system to protect individuals' fundamental guarantees and rights based on the dignity of the human person, a foundation of the republic and the basis for all legal relations [21]. The current interpretation—no one should be discriminated against on the basis of their genetic information—fails to exclude the need to regulate access to DNA in detail.

Investments in precision medicine are exponentially growing worldwide, including in the form of studies and research dedicated to the application of knowledge in the diagnosis and treatment of diseases. This is the case, as highlighted by Collins and Varmus [22], of the Precision Medicine Initiative, a North American program aimed at promoting research involving precision medicine, linked to National Institutes of Health (NIH).

Historically, in countries such as Brazil, the relevance of programs aimed at the prevention and management of genetic diseases has been questioned in general. One should consider the high morbimortality rate of such diseases, their exponential increase, and the need for continuous treatment [23]. Such diseases are often underdiagnosed, which implies losses of

opportunities for prevention and early advice, generating costs for patients and public or private health systems which could be optimized [24].

The pattern of global epidemiological manifestation is relevant to the purpose of precision medicine when the growth of chronic-degenerative diseases is observed. Although it can be considered that environmental factors directly influence the formation of this epidemiological prevalence, the importance of early diagnosis and the choice of personalized treatment should be emphasized [11].

The global growth in health spending is undeniable and is independent of the economic health of countries. The increase in life expectancy (expressed in the widening of the age pyramid), the change in the global epidemiological profile, and the general advances in new scientific possibilities make up the overview of factors that contribute to greater public and private health spending [5].

The use of genetic data to predict neoplastic diseases and choose appropriate treatments for individuals' response capacity are the main contributions of precision medicine to health costs. In addition to improving patients and families' health and life outcomes, the possibility of needing the most appropriate treatments may reduce expenses with ineffective treatments [5].

Inadequate treatments can have two-fold repercussions: the first and most important are side effects and iatrogenic injuries, that is, caused by the very inefficiency of treatments which fail to represent the best choices in terms of clinical possibilities. The second repercussion is economic since such treatments may symbolize significant and avoidable ongoing expenses, if we consider more appropriate alternatives [5].

The study of genetics in the field of precision medicine is a gradual and dynamic process that has been consolidated. It is known that providing therapeutic technology and resources is a decision that requires often difficult, imperfect, and incipient evidence collection [25].

In line with the proposed Statute of the People with Cancer [1], a large-scale study should be carried out on the potential economic impact of prediction as an anticipatory and personalized measure in neoplastic diseases [5] as a premise to expand coverage for supplementary or public health.

In Brazil, Law 13,709 (General Data Protection Law) [26], approved in 2018 and effective as of 2020, stipulated rules on the use, protection, and transfer of personal data, also covering genetic data, which it classified as sensitive. The law conditioned, as a rule, the use of such data on informational self-determination, that is, on the express authorization of data subjects.

Access to precision medicine resources—especially from the perspective of oncogenetics—is limited in Brazil by fundamental regulatory acts which are often strictly economic. Their impacts on the use of genetic tests show results that justify the need to rethink the restrictions on SUS and supplementary health coverage [5].

As an obstacle to the incorporation of the multiplicity of genetic tests—especially those on predisposition—into the list of coverage by health plans, an argument of adverse selection is used. According to this perspective, people who are more likely to have health problems would seek insurance companies more often, while those with a lower predisposition to illnesses would demand fewer medical services. This would increase the scope of this type of contract [25].

Adverse selection fails to constitute an argument to prevent the expansion of genetic testing coverage by health plans. The first basis for this expansion, in fact, lies in the constitutional idea of the right to health itself. It is impossible to support with purely economic arguments impediments to the adequate implementation of the law since scientific evidence points to the positive repercussion of the use of this type of resource on the impact on patients and their families' lives [5].

Another basis pervades the prerogative of the regulatory act (involving Anvisa and ANS) and must consider, based on the medical-scientific indicators, which tests should be covered and who can request them. The competence to establish which tests, among the thousands available, may be requested in the context of supplementary health care is one of the vectors that must be used to limit a possible increase in the price of plans. This decision must be scientifically based, justifying coverage based on evidence and economically considering the tests which must belong to the list of those to receive funding [5].

It should also be added that the position of the Superior Court of Justice (STJ) regarding the nature of the list of mandatory coverage procedures devised by the ANS [27] regulatory instruments remains pending. It is discussed whether this is exhaustive or merely illustrative, as expected by society at large.

SUS, the largest health system in the world, is based on the principles of universal access and comprehensive care set out, among others, by Law 8,080/1990 [28]. The use of precision medicine may impact, on a large scale, the reprogramming of spending on the public health financing system, especially regarding cancer treatments. One must reprogram this coverage policy to contemplate the predictive dimension of medicine, with the objective of reducing costs with non-personalized treatments [5].

Genetic counseling and testing, for example, must constitute the protocol for the care of patients and their families in the context of primary health care. Ordinance 81/2009 [29] of the Ministry of Health established, in SUS, the National Policy for Comprehensive Care in Clinical Genetics (PNAIGC), whose purpose is the organization of a comprehensive care line involving prevention and treatment, covering all levels of care, including primary care.

However, *the public service in genetics is unable to adequately reach the population since public education policies and access to health care, its minimum organizational structure, as well as the training of Primary Care professionals are non-existent or insufficient* [30].

Regulations imposed by the ANS regarding the coverage of genetic tests on individuals' predisposition to cancer recently introduced new regulations establishing that, regarding the oncogenetic guidelines for multiple affected individuals in the same family, the youngest individual suffering from a typical tumor in the evaluated spectrum should be initially and preferably tested [31].

Moreover, the aforementioned resolution adds that when a mutation is identified in the family, unaffected members may also be tested, as defined in each of those specific guidelines. However, in all cases of genetic testing in family members, coverage will be mandatory only when the family member being tested is a beneficiary of a health plan [31].

One may notice the persistence of the criteria for requesting the test, performed only when the individual was diagnosed with cancer. The possibility of extending these tests to patients who have never had cancer will only occur in cases in which a mutation has already been identified in the family [5].

Under these regulations, coverage of molecular DNA analysis (genetic tests) is optional in cases of *personal risk screening or family planning screening in an asymptomatic patient* [32], corroborating the limiting interpretation of this type of test in patients without a diagnosis of oncological disease. Thus, if *testing is recommended based on a family history highly suggestive of hereditary cancer syndrome in a family where all cases diagnosed with cancer have already died, the list does not include testing the descendants of cancer patients* [33].

In public health, the PNAIGC proposes the use of genetic counseling as an initial predictive tool but fails to provide for the possibility of covering tests to accurately assess individuals' predisposition to cancer [29]. So genetic counseling can become a reality capable of altering results, it would also be necessary to invest in health education for the population, in the organizational structure of healthcare, and in the training of primary care professionals.

The Statute of the People with Cancer [1] confirmed the fundamental rights and guarantees of cancer patients, which could previously be extracted from the interpretative logic of the Constitution. However, it provided detailed information on the grounds that contribute to the prompt and adequate judicial protection of those who fight for decent treatment in the fields of supplementary public health while maintaining the hope of containing the progression of the disease [1].

Early diagnosis and the possibility of preventing cancer occupy prominent positions in the law, confirming the importance of precision medicine aimed at a more personalized view of treatment. The Statute [1] therefore contemplates the need to rethink the legal discipline of cancer based on a purely curative sphere, that is, when

the disease is already established or even shows significant progress.

Recently, Law 14,307/2022 [2], which provides for the process of updating coverage in the field of supplementary health, defined rules for the incorporation of new treatments. Attention should be paid to the pending trial by the Brazilian Supreme Court regarding the nature of the list of treatments and medications defined by ANS. The court will determine whether it reveals an exhaustive or a merely illustrative list [27].

Law 14,307/2022 2 made it mandatory to cover oral and home treatment for oncological diseases, with approval of drugs by Anvisa [2]. It also determined the priority to process administrative proceedings regarding the incorporation of new drugs and chemotherapeutic treatments. Moreover, inclusion in the ANS list should take place within 120 days from the date on which the request was filed. If the deadline has elapsed without evaluation by the ANS, the drug should automatically be included in the list [2].

Brazil has seen important changes regarding its legislative framework focused on the rights of cancer patients in recent years. The tendency to incorporate and extend coverage is based on speed, which is fundamental to any treatment aimed at neoplasms.

Legal claims regarding the complex of possibilities involving cancer treatment are substantially based on the emergence of important therapeutic alternatives persistently uncovered by SUS or supplementary health care [5].

It is essential to establish an articulated national plan among public agencies and academic centers to create and implement genetic counseling for patients at high risk of cancer. Thus, one can guarantee universal access to personalized screening strategies and reduce the risk of cancer through the knowledge of oncogenetics [4].

Final considerations

The possibility of predicting the probability of the manifestation of oncological diseases or the ability of thoroughly analyzing it to build a personalized prevention or treatment strategy is a real proposition of precision medicine which originates from access to genetic tests. This proposal makes it possible to rethink the exclusively curative dimension of the right to health, that is, the one linked to the idea of seeking a cure or stagnation of the disease after it is already established.

Predictive tests make it possible to identify genetic mutations related to the probability of neoplastic diseases to draw up appropriate strategies for each case. The hereditary characteristics of cancer may justify the choice for prophylactic or preventive strategies such as surgeries to remove organs, more appropriate and frequent screening tests, and the use of personalized medications to reduce the chance of the disease developing.

The latest legislative changes were important to advance access to predictive genetic testing, but both SUS and supplementary health still conform to limits requiring reconsideration.

Regarding health insurance coverage, it is necessary to reassess the impediment to the examination of patients undiagnosed with cancer (but with a significant family history of the disease) and the restriction of the possibility of requesting examinations only by professionals from certain specialties, even if other professionals have accentuated knowledge and need to do so.

The lack of adequate public policies aimed at carrying out genetic tests to treat patients with an important family history—whether diagnosed with the disease or not—at SUS violates individuals' fundamental and adequate access to rights. This economic basis delegitimizes this restriction of access in the public and private spheres since it evinces that the contingency of expenses is unable to void the right to survive.

The law is responsible for continuing the movement initiated with Laws 14,238/2021 [1] and 14,307/2022 [2] to incorporate medical possibilities that reflect social interests and promote the adequate and prompt protection of legal assets. Moreover, there is the necessary adaptation of the performance of the Brazilian superior courts in matters related to the subject since the legislative process and the actions of the Executive are unfortunately unable to timely implement legitimate oncological demands.

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Both authors contributed to the conception and writing of the article, the critical review of its content, and approval of the final version.

Received: 5.2.2022

Revised: 9.6.2022

Approved: 9.15.2022