

Legal aspects of the development of optical medicine for severe systemic diseases

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ABSTRACT

The article is aimed at the development of a new multiparameter polarimetric approach for new methods of Mueller-matrix polarization-phase tomography based on the differentiation of polarized and depolarized components and for reproducing the distributions of birefringence value, a set of solutions to the inverse problem - algorithms for polarization reproduction of the distributions of the phase parameters and linear and circular dichroism to determine objective criteria for early diagnosis and differentiation of pathology stages. Modern public health is comprehensive in its goal, as it refers to measures aimed at both the entire community and individual health needs. A number of such measures are focused on improving the human environment, reducing risk factors that form a significant burden of disease and mortality among the population and stimulating those factors that, on the contrary, contribute to the promotion and preservation of health.

Key words: new multiparameter polarimetric approach, early diagnosis and differentiation of pathology stages, socio-economic transformations, statistical monitoring

1. INTRODUCTION

Disorders and diseases of the musculoskeletal system (DMSS) are more than 150 health disorders affecting the musculoskeletal system. They range in a wide range: from acute and short-term events - fractures, sprains and dislocations - to lifelong disorders, accompanied by a permanent decrease in functionality and disability.

Disorders and diseases of the musculoskeletal system are usually characterized by painful sensations (often of a permanent nature), decreased mobility, deterioration of motor skills and functional capabilities in general, which limits a person's ability to work.

DMSS includes disorders affecting joints such as osteoarthritis, rheumatoid arthritis, psoriatic arthritis, gout, ankylosing spondylitis. Data from a recent Global Burden of Disease study show that approximately 1.71 billion people worldwide suffer from musculoskeletal disorders and diseases¹.

High-income countries (441 million) are most affected by such diseases, followed by the Western Pacific Region (427 million) and the South East Asia Region (369 million).

Disorders and diseases of the musculoskeletal system also occupy a leading place among the factors of disability in the world: they account for approximately 149 million years of life lived with disabilities, which globally accounts for 17% of all years lived with disabilities due to various causes.

The number of people suffering from joint disease is projected to only increase in the future, with the fastest growing rates in low- and middle-income countries².

In Ukraine, more than 80% of the population suffer from pathologies of the musculoskeletal system, 90% of children have postural disorders, and 20% are diagnosed with scoliosis³⁻¹⁰.

From a physical point of view, such a problem lies in the fact that it is scientifically relevant: - formation of relationships between the structure of polycrystalline networks of films of biological fluids and layer-by-layer distributions of azimuthally invariant Mueller-matrix maps, elements of polarized (polarization-phase tomogram) and depolarized (diffusion tomogram) components of the differential matrix; - development of methods for multi-parameter statistical, correlation and fractal processing of experimentally obtained polarization-phase and diffusion tomograms of optically anisotropic structure of prototypes and determination of a set of new objective criteria for early detection of pathologies of human organism.

2. LEGAL ASPECTS OF THE FORMATION OF OPTICAL MEDICINE

The socio-economic transformations that took place during the years of Ukraine's independence, the development of modern information technologies, and the introduction of new organisational and legal forms of healthcare institutions have led to the need for its significant transformation. The reforms carried out in the sector have affected not only the basic issues of organisation of various types of medical care to the population and financial guarantees for its provision,

but also statistical monitoring of the state of resource provision, public health, and certain aspects of the activities of health care institutions³⁻¹⁰.

The need to study the strategy of health care development in the context of modernisation is dictated by the decline in the number of Ukrainians, the desire to develop effective solutions in the field of health care in the context of new political, economic and social realities. The unresolved acute medical and social problems necessitate the development and implementation of innovative high medical technologies, which is impossible without further improvement of the healthcare system of Ukraine.

The European Social Charter (Revised) enshrines the international legal norm on the right to health among the fundamental social rights, while providing for the obligation of States Parties to this Convention, such as Ukraine, "to adopt, either alone or in co-operation with public or private organisations, appropriate measures aimed at, inter alia, the provision of counselling and educational services to promote health and encourage personal responsibility for one's health"⁷.

Modern public health is comprehensive in its goal, as it refers to measures aimed at both the entire community and individual health needs. A number of such measures are focused on improving the human environment, reducing risk factors that form a significant burden of disease and mortality among the population and stimulating those factors that, on the contrary, contribute to the promotion and preservation of health. The programme focus of such measures varies widely from immunisation strategies, health promotion and childcare, food labelling and fortification (increasing the content of vitamins and minerals in food to improve the nutritional quality of food and have a positive effect on human health) to guaranteeing quality organised and accessible healthcare services⁹. In addition, human health is influenced by such a factor as the state's health policy and its views on the development and implementation of innovative areas and methods in the field of medicine.

The theoretical and methodological foundations of the analysis of health policy in the context of modernisation lie in the plane of intersection of such sciences as political science, sociology, medicine, social psychology, taking into account the theoretical and conceptual foundations of socio-political institutions, theories of public administration and are usually interdisciplinary. Health policy is the art of managing the health of the population. It is a state, public and professional activity in the field of healthcare aimed at preserving and improving the health of the population. Its goal is to provide legal, economic and social guarantees for each individual in terms of formation, strengthening and preservation of health, in accordance with generally accepted international legal norms and the Constitution of Ukraine¹⁰. As a member of the United Nations (UN), Ukraine has joined the implementation of the Sustainable Development Goals through the development of relevant national strategic objectives, with special attention paid to the establishment and division of powers in the field of public health between stakeholders and the development of public health programmes⁹. The Decree of the President of Ukraine enacted the decision of the National Security and Defence Council "On the state of the national healthcare system and urgent measures to provide medical care to Ukrainian citizens". It is this decision that should be used as a basis for the Strategic Plan for the Development of the Public Health System until 2030. The Strategic Plan should ensure that every citizen, regardless of gender, age, financial status, receives quality healthcare services guaranteed and paid for by the state and has equal access to them, and should provide a standard integrated model that provides for the comprehensive provision of healthcare services throughout the entire human life cycle.

Collaboration between doctors and engineers has led to new ideas, directions, and requests from the medical community. Computer monitoring technologies have led to progress in the development of software for processing primary data and have radically changed the worldview of a modern doctor. Today, a practitioner understands that he or she needs not just a blood pressure (BP) machine, but a device that measures pressure, records its parameters and displays the dynamics of changes in these parameters on the monitor in the form of a diagram or bar chart depending on the drug effect on the body⁸. The European Parliament's Resolution of 16 February 2017 notes that humanity is on the verge of an era of much more high-tech robots, which symbolize the beginning of a new industrial revolution that will affect all segments of society. Therefore, it is important that the established ethical and legal norms do not suppress the development of innovations⁶. Starting to study an unknown biological object or phenomenon, the researcher seeks to obtain the most complete and reliable information. To do this, he or she has to use various methods and ways of obtaining information about the object. The effectiveness of obtaining this information depends on the experimenter's knowledge of research methods and the ability to apply them depending on the tasks at hand. Such skills have been developed and substantiated in a new Mueller matrix model of biological layers with phase and amplitude anisotropy⁴, which will make it possible to diagnose and detect severe systemic human diseases at an early stage. This model will make it possible to perform various kinds of manipulations with hard-to-reach areas of the musculoskeletal system directly during surgical operations and increase their accuracy, improve rehabilitation prognoses and help people with disabilities in everyday life. In addition, it will allow us to achieve qualitatively new results and provide new discoveries in both clinical practice and biomedical

technology. When setting standards of medical practice, it is important to remember that the treatment of severe systemic diseases is not just a technical problem, but above all an ethical, legal and social challenge. Taking this seriously will require careful interaction directly with the healthcare system, public authorities, and stakeholders to jointly develop new directions and technologies from the beginning of their implementation to their evaluation. Undoubtedly, new methods and technologies in the process of their implementation should be interconnected in the provision of medical care using remote communication means for exchange, namely telemedicine, which aims to improve the physical and psychological health of the population based on the principle of equal access to medical services. For example, telemedicine has many applications in ophthalmology, as it requires visual images for diagnosis, therapy and disease monitoring. Ophthalmology has quickly adapted to the cyber world and uses the telemedicine technology system to access advanced medical care. As early as 2017, Specsavers announced that each of its more than 700 branches would have an optical coherence tomography device by the end of 2019⁴.

The effective use of telemedicine has demonstrated both economic and health benefits⁵. For example, telemedicine can improve the quality of care for two important ophthalmic diseases, such as diabetic retinopathy (DR) and retinopathy of prematurity (ROP). DR is the leading cause of blindness among working-age adults. Telemedicine programs provide screening of patients with DR in primary care⁵.

Thus, the spread of ophthalmology apps will facilitate access to retinal screening or ophthalmological tests with appropriate frequency. Telemedicine in ophthalmology is useful for monitoring intraocular pressure and macular disease⁶. Thus, the main factor that contributed to these processes was the progress in treatment methods, thanks to the introduction of the latest trends and technologies that allowed to reach a new level, allowing doctors to see pathological processes that cannot be seen during a routine examination. The main goal of this transformation is to improve the diagnosis of severe systemic diseases, predict its stages and provide effective treatment and advanced medical services.

The latest trends and technologies can be successfully applied in various fields of modern medicine. For example, in the area of patient safety, modern automated systems can enhance quality control and safety of medicines and medical services, reduce the likelihood of medical errors, provide emergency assistance by means of rapid communication and access to vital patient information. Modern technological solutions can provide free access to healthcare services regardless of the patient's place of residence, and significantly increase the availability of high-tech medical services and medical expertise. The introduction of innovative trends and technologies will help create an efficient healthcare system, which will also help improve the quality of medical services. All of this can lead to a higher level of public health, lower mortality rates, and longer life expectancy. All of this is impossible without reforming the healthcare system, which cannot be reformed without reliable information in this area.

Any changes in the social space caused by the introduction of new technologies do not occur in isolation, and therefore have various socio-economic consequences. The development and application of the latest trends and technologies, automated technical systems in the healthcare sector have a powerful potential, as they actualize the social role of law, whose task is to properly regulate and protect emerging relations that have been in a regulatory vacuum until recently¹¹⁻¹⁵.

The legal influence on relations in the field of development of innovative directions and technologies at the present stage is aimed at promoting technological progress, ensuring a qualitatively new level of health of citizens in the provision of medical services with the help of new directions and technologies. This goal covers the full stages of development and use of innovative areas, technologies, methods of medical diagnostics and is of a sectoral, inter-sectoral and institutional nature, which allows the whole system of legislation to be used to achieve this goal. This includes legislation on healthcare, scientific and technical activities, social services and social protection, civil law, labor law, personal data legislation, etc. At the same time, the adaptive dynamics of sectoral regulations to rapid innovation changes, including technological ones, is different: technical regulation easily reflects the normative characteristics of new technologies, while the scope of legal regulation of the use of technological processes is rather conservative. It should also be noted that the ability of legislation to adapt to innovative trends and technologies depends on various political, social, economic and cultural factors. From a legal point of view, it is necessary to improve legislation, in particular, regarding approaches to methodological development of measures for legal regulation of social relations in the field of modern medical innovation, which would provide for the anticipatory and conceptual nature of lawmaking; legal justification of draft regulations that will ensure innovative areas in medicine; preparation of predictive models and legal monitoring at each stage of preparation of such projects; application of modern legal technologies. When drafting regulations, it is necessary to formulate the basic principles of regulation in the legislation with regard to: conceptual framework, security measures, delimitation of powers of state bodies responsible for ensuring, developing and financing innovative areas and technologies. It is necessary to reflect the norms designed to ensure integration with local legal practice and taking into account local, geographical

features, to formulate professional and ethical standards in cooperation with professional communities and civil society institutions.

CONCLUSIONS

In order to achieve this goal and outline important approaches to the necessary legal transformation, it is of particular importance to provide a theoretical and legal basis for determining the place and importance of innovative trends and technologies in the system of law and legislation. The main principles of legal regulation should be the principle of humanism, which forms the basis of the legal system and is built around the highest value of a person - his or her life and health. Accordingly, when forming the legal system with an allowance for the existence of innovative areas, technologies, and methods of medical diagnostics, it is necessary to systematically implement the intended goals and objectives and create an updated legal framework.

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