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PROBLEMS OF REGULATING THE QUALITY OF MEDICAL CARE IN UKRAINE AND THE MAIN DIRECTIONS OF THEIR SOLUTION

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Ключевые слова: *качество медицинской помощи, аккредитация, лицензирование, сертификация, стандартизация*

Abstract. Problems of regulating the quality of medical care in Ukraine and the main directions of their solution.

Tolstanov O.K., Krut A.G., Dmitrenko I.A., Gorachuk V.V. *Improving the quality of health care remains problem of the day for world health systems. Recognized quality management tools are used in Ukraine. However, a series of studies indicate the need for their improvement.. The aim of this work was to determine the features of the application of international instruments for regulating the quality of medical care and to substantiate the conceptual directions of their improvement in Ukraine. Materials and methods of research used: systemic approach; comparative analysis; bibliosemantic; conceptual modeling; scientific literature sources, including systematic reviews from the PubMed database; domestic legal documents. Main results: unlike international practices, professional activity of doctors is not licensed in Ukraine. The economic activity of health care institutions and individuals-entrepreneurs engaged in medical practice is subject to licensing. Accreditation standards have not been revised since 2013. Domestic adaptation of clinical guidelines has been suspended for several years. Certification of quality management systems is administratively related to accreditation. All quality management tools are strictly regulated by the Ministry of Health, without the involvement of local governments, public patient organizations and health professionals. Conceptual directions of improvement of tools of quality regulation are offered: adoption of the law on professional licensing of doctors; creation of an independent accreditation agency; updating the content of accreditation standards, supplementing them with patient safety standards in accordance with international criteria; creation of methodological support for accreditation and certification; training of accreditation inspectors; introduction of tracer methodology in order to verify compliance with accreditation standards; resumption of adaptation of international clinical guidelines at the health sector.*

Реферат. Проблемы регулирования качества медицинской помощи в Украине и основные направления их решения. Толстанов О.К., Круть А.Г., Дмитренко И.А., Горачук В.В.

Проблема улучшения качества медицинской помощи остается актуальной для мировых систем здравоохранения. В Украине используются общепризнанные в мире инструменты регулирования качества. Однако ряд исследований указывает на необходимость их совершенствования. Цель исследования – определить особенности применения международных инструментов регулирования качества медицинской помощи и обосновать концептуальные направления их усовершенствования в Украине. Методы и материалы: системного подхода; сравнительного анализа; библиосемантический; концептуального моделирования; научные литературные источники, в т. ч. систематические обзоры из базы данных PubMed; отечественные нормативно-правовые документы. Основные результаты: установлено, что, в отличие от международных практик, в Украине лицензируется не профессиональная деятельность врачей, а хозяйственная деятельность учреждений здравоохранения и физических лиц-предпринимателей, занимающихся медицинской практикой; стандарты аккредитации не пересматривались с 2013 года. Отечественная адаптация клинических руководств приостановлена;

сертификация систем управления качеством административно связана с аккредитацией. Все инструменты управления качеством жестко регулируются Министерством здравоохранения, без привлечения представителей органов местного самоуправления, общественных организаций пациентов и медицинских работников. Предложены концептуальные направления усовершенствования инструментов регулирования качества: принятие закона о профессиональном лицензировании врачей; создание независимого агентства по аккредитации; обновление стандартов аккредитации, дополнение их стандартами безопасности пациентов в соответствии с международными критериями; внедрение методического обеспечения аккредитации и сертификации; подготовка инспекторов по аккредитации; внедрение методологии трейсера при проверке соблюдения стандартов аккредитации; возобновление адаптации международных клинических руководств на отраслевом уровне.

Improving the quality of medical care is embedded in the essence of the concept of quality as a philosophical and socio-economic category. Quality is determined by the unique characteristics of a product or service, which distinguish them from other types of goods or services and can satisfy consumer requests [8, 25, 28].

World health care systems are in a long-term search for approaches to improving the quality of medical care, based on its actual characteristics for patients. According to the definition of the WHO (2018), these are clinical effectiveness, safety, patient orientation, financial availability, timeliness, fairness, comprehensiveness, economic efficiency [9]. In order to achieve quality characteristics, various regulatory tools are used: licensing of professional activities of doctors, accreditation of health care facilities, certification of quality management systems, standardization of medical technologies.

Licensing of the professional activity of doctors has been widespread in most European countries since the 19th century and is considered as a way to protect the patient from low-qualified doctors [20].

The active progress of the world system of standardization of medical technologies began in 1992. The world's leading scientific centers collect scientific evidence of the best clinical practice, develop, adapt and implement clinical recommendations in order to ensure the quality of medical technologies [19, 21].

Accreditation has gone from a purposeful system in the USA, initiated by the College of Surgery in 1917, to the most authoritative international accreditation system Joint Commission International (JCI), focused on the patient and the management of a medical organization [14].

The development of international ISO standards for quality management systems took place through the creation of standards of the 9001 series of versions of 1994 and 2000, among which specific standards for medical organizations were also developed, in particular "Quality management systems – EN ISO 9001:2015 for healthcare" [17].

In view of the above, at the international level, the listed instruments are constantly being improved. The implementation and use of updated tools by management bodies and health care institutions, bodies and associations that carry out accreditation, certification and development of clinical guidelines contributes to increasing the safety and efficiency of medical care [6, 10, 27].

Scientific studies of domestic authors [1, 3, 32] proved the imperfection of accreditation of health care institutions, licensing of medical practice, and standardization of medical technologies in Ukraine, which were considered separately. At the same time, the problem of improving the quality of domestic medical care from the standpoint of a comprehensive analysis of compliance with content and the use of international quality control tools was not investigated, which determines the relevance of this work.

The purpose of the study is to reveal the peculiarities of the use of international tools for regulating the quality of medical care in Ukraine and to substantiate the conceptual directions of their improvement in the national sphere of health care.

MATERIALS AND METHODS OF RESEARCH

A comprehensive comparative analysis of requirements and procedures for licensing, standards and procedures for accreditation of health care institutions, certification of quality management systems, standardization of medical technologies in Ukraine and other countries of the world was carried out. The results of the analysis served as the basis for the justification of the conceptual directions for improving the tools for regulating the quality of medical care in the national sphere of health care using the following methods: a systemic approach; bibliosemantic, conceptual modeling.

Research materials were scientific literary sources, in particular systematic reviews and meta-analyses from the PubMed database, recommendations of international experts, domestic legal documents.

RESULTS AND DISCUSSION

The results of the study established that licensing in health care in the countries of the European Union and the USA is aimed at guaranteeing a high level of training and qualification of doctors, which is a necessary condition for ensuring the clinical effectiveness of medical care. The object of licensing is the professional practice of a doctor. Based on the results of passing the licensing procedure, which includes a licensing exam, a doctor receives a license, i.e. a legal permit for professional activity. Finally, the permit is implemented through the registration procedure in special registers or cadastres. Licensing and registration relay, depending on the country, on various regulatory bodies - licensing subjects – from ministries and other state organizations, in particular at the regional level in federal countries, to medical chambers and professional medical associations [23].

The extension of the validity period of the license is possible if the doctor complies with the requirements of continuous postgraduate training and there are no lawsuits, patient complaints and negative work results for a certain period of time. Thus, licensing ensures the formation of personal responsibility of the doctor and motivates him to constantly maintain a high professional level [31].

In Ukraine it is not the professional activity of a doctor that is licensed, but the economic activity of medical practice of health care institutions and individual entrepreneurs. In the event of termination of the license, a legal entity or an individual entrepreneur loses the opportunity to conduct economic activity in medical practice, but their doctors can continue their professional activities as employees in other institutions or with another individual entrepreneur. It is clear that under such conditions, licensing is not a motivating factor for raising the professional level and improving the doctor's work. The subject of licensing in Ukraine is exclusively the Ministry of Health (MoH), and a license is issued only on the basis of submitted documents according to the established list, by correspondence procedure. The validity of data is not checked on the spot for issuing a license [12].

Certain steps towards the introduction of licensing of doctors in Ukraine have already been initiated, in particular the system of continuous professional development [7]. In June 2018, the project "Concepts of Professional Licensing of Doctors" was developed. According to the authors of the article, the project should be approved as a strategic document, which presents a "road map" for doctors' access to professional activities and support for

continuous professional development, which will fundamentally affect the improvement of the quality of medical care.

Standardization of medical technologies is an instrument of clinical efficiency, as well as the safety of medical interventions and their economic efficiency, especially if the doctors have a high professional level. It is known that clinical guidelines developed using clinical evidence of systematic research are able to improve the quality of medical care. The development and distribution of clinical guidelines and indicators of the effectiveness of health care services is carried out by the Central Agency of Great Britain – the National Institute for Health Protection and Healthcare Excellence (NICE), as well as the Scottish Interuniversity Guidelines Network (SIGN). Centralized agencies of Germany, France, Australia, the USA and Canada coordinate the implementation and approval of clinical guidelines developed in accordance with the accepted world standard by any subject of the health care system. Most low- and middle-income countries develop their own clinical guidelines without centralized approval and coordination, but the quality of such guidelines has been shown to be low and to vary both within and between countries. There is also a group of countries that do not develop their own recommendations. These are mainly countries with a low level of economic development and political instability, including Ukraine [16].

Standardization of medical care in the domestic field of health care took place through adaptation to the national conditions of NICE clinical guidelines and the development of sectoral Unified Clinical Protocols of Medical Care (UCPMC) by multidisciplinary working groups. Successfully started, this path has been bumpy, as over the past several years the mentioned activity has been suspended, then resumed, but is currently progressing at a slower pace. Over the past year, it has been focused mainly on the adaptation of clinical guidelines, standards and protocols for the organization of medical care, diagnosis and treatment of the corona virus disease (COVID-19).

The Ministry of Health of Ukraine declared the possibility of using the so-called "new" clinical protocols, that is, the use of clinical guidelines developed in other countries and/or international organizations, without a national adaptation procedure, when the responsibility for their selection, translation, and implementation rests with the health care institution. This creates threats to ensure uniform approaches to standardization of medical care at the national level and coordination of actions

of different types of institutions and stages of providing medical care to a patient who needs it. At the level of a health care institution, it is impossible to resolve the issue of the use of medicinal products and medical products not registered in Ukraine, the use of medical and diagnostic technologies in the absence of them in the domestic sphere of health care [13].

In Ukraine, there is still a base of medical care standards, developed by experts, recommended for use in clinical practice. It is clear that the treatment and diagnosis of diseases according to these standards does not provide high guarantees of clinical results, since the strength of expert opinions is the least compared to the clinical evidence of systematic studies.

Thus, the standardization of medical technologies in Ukraine needs to be revived in the direction of further adaptation of clinical guidelines, development of sectoral UCPMC for the most common and significant diseases in terms of social consequences, and revision of these documents created more than five years ago. Further development of patient routing, aimed at coordination of various types and stages of medical assistance, its timeliness, continuity, multidisciplinary and complexity, requires special attention.

Accreditation of health care institutions in the countries of the world is based on an external independent assessment of the ability to perform specific tasks of providing medical care in accordance with predetermined criteria. As a rule, such an assessment is carried out by non-governmental non-commercial structures, and external auditors are highly professional experts in the field of medical practice.

Today, global systems of accreditation of medical organizations are rapidly developing, as evidenced by the emergence of accreditation standards and procedures beyond national borders, the development and implementation of international accreditation programs and the functioning of independent institutions – quality and accreditation centers, commissions, services, accreditation agencies, which develop and update accreditation standards, provide consulting services on their implementation, conduct inspections (audits) on compliance with standards in various countries of the world [15, 24, 26, 33].

International accreditation standards are aimed at achieving such a quality characteristic as patient-centeredness through the fulfillment of requirements for the safety of medical care, as well as quality management of medical organizations. For example,

the JCI accreditation standards for hospitals are highly differentiated by areas of activity and types of medical care and reflect requirements for patient safety: admission, transfer, discharge; patient identification; prevention of falls; surgical and epidemic safety; the safety of the use of medicines; continuousness of treatment; effectiveness of communications; respecting the rights of patients and their families; personnel training; administrative and economic management of the institution and safety equipment; information management, formation of safety culture, etc. These standards are reviewed and updated every year in accordance with the development of medical and organizational technologies, requests of patients, medical workers, etc. [18, 22, 30].

The actual accreditation standards, the accreditation procedure and the organizational structure that ensures it should be considered problematic areas of domestic accreditation.

Accreditation standards in Ukraine are outdated, as they were developed in 2011, changes and additions were made only in 2013, the current latest version of the order of the Ministry of Health of Ukraine, which approves accreditation standards, took place in 2014 [11]. The analysis of the content of the standards showed that they are mainly aimed at identifying the provision of the health care institution with regulatory documents and, in certain positions, require verification of their compliance during the accreditation procedure. According to [5], 40.1% of accreditation standards repeat licensing requirements, which discredits accreditation as a powerful tool for quality improvement given that licensing requirements are aimed at ensuring only a minimum level of quality of medical care.

Accreditation, like licensing, takes place within the departmental space, since the Main Accreditation Commission of the Ministry of Health of Ukraine and the accreditation commissions created at the structural divisions of health care of regional/city state administrations are empowered to carry out accreditation; procedures for preparing and carrying out accreditation are not methodologically ensured; verification of compliance with accreditation requirements is not permanent.

Accreditation in Ukraine, introduced at the end of the 90s of the last century, only from 01.01.2019 following the example of international accreditation systems became voluntary in nature, but there are no mechanisms to motivate health care institutions to undergo accreditation, in particular in terms of payment for the provided

medical service under the state program of medical guarantees.

According to the model of international accreditation programs, the base of domestic standards must be supplemented with patient safety standards determined at the international level [4], it is necessary to develop standards as separate documents for different types of health care facilities (hospitals, outpatient clinics), types of medical care (emergency, primary, secondary, tertiary, rehabilitation, palliative), clinical conditions of patients according to the most socially significant nosologies with requirements for carrying out measures, manipulations, procedures at the doctor-patient level, where the quality of medical care is directly formed.

The above-mentioned requires improvement of the methodology of development of national accreditation standards, in particular the involvement of interested parties in this process (experts, medical workers, scientists, representatives of public organizations of patients, governing bodies of territorial communities, others).

A promising task is the creation of an independent accreditation body, to which the Ministry of Health of Ukraine will transfer the functions of developing accreditation standards and the functions of creating methodological guidelines for accreditation, consulting services, carrying out the procedure of preparation and actual accreditation of health care institutions and post-accreditation monitoring.

An urgent issue is the preparation and certification of the contingent of domestic inspectors for accreditation and the introduction of the tracer methodology when they implement the accreditation procedure and monitor compliance with accreditation standards. The specified methodology provides for a clear redistribution of inspectors' (auditors') time to review processes (60.0-70.0%) and work with documents (30.0%). The review of processes consists in direct communication with the patient and medical workers in order to register the actual actions in their sequence and content that took place on the patient's route, followed by a comparison of the received information with the requirements of the relevant standard and analysis of deviations [2].

Certification of quality management systems in accordance with ISO 9001 standards in the field of health care allows managers to better navigate the medical and diagnostic process and other activities of the medical organization, necessary for its support

and improvement. Researchers consider the implementation of risk management focused on patient safety, constant monitoring and internal audit of processes, management of resources, in particular financial and personnel, and periodic determination of the level of patient satisfaction to be an important achievement of certified quality management systems. This ensures the achievement of such quality characteristics as timeliness, fairness, comprehensiveness, economic efficiency [29].

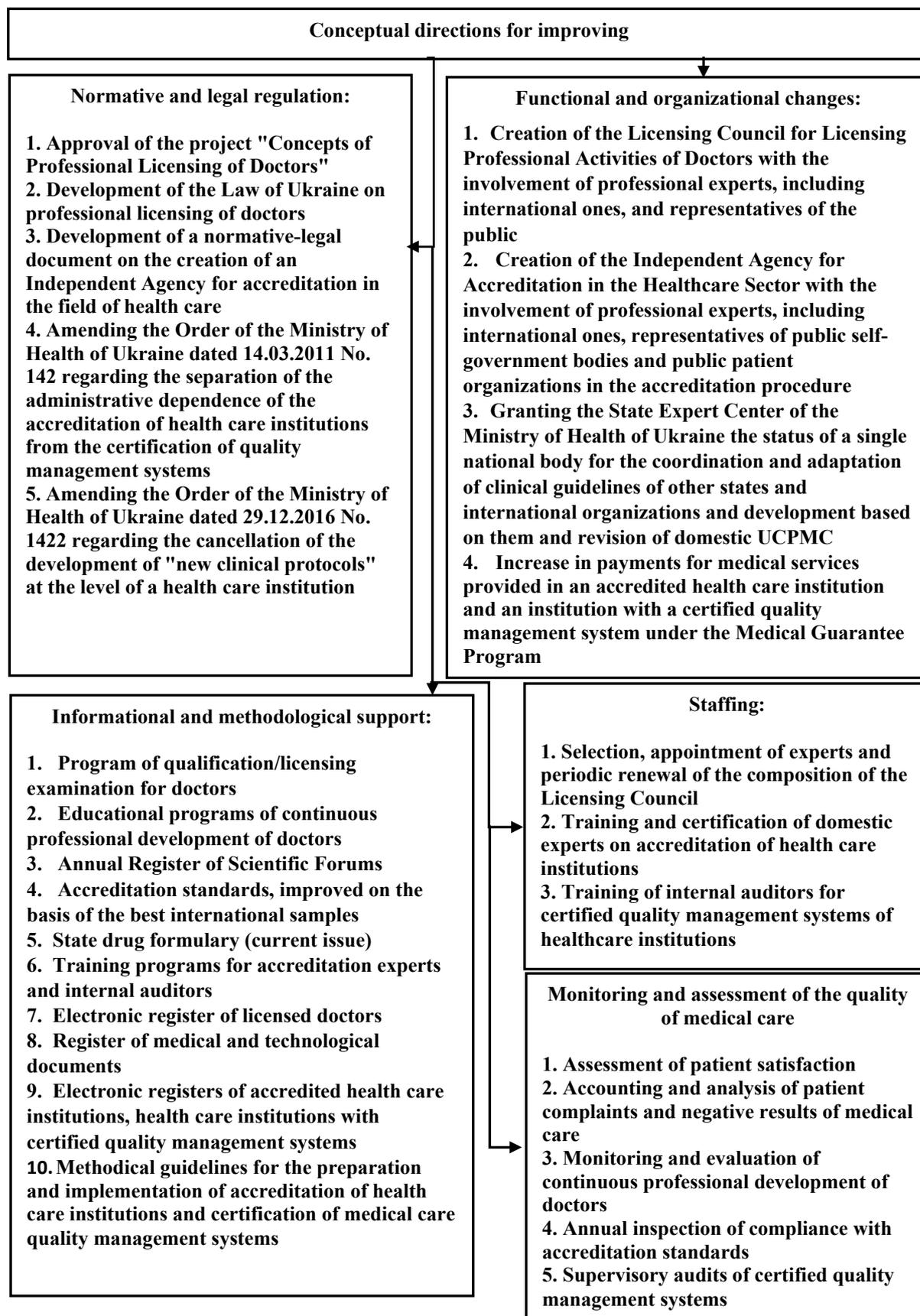
Certification of health care institutions in Ukraine, unlike other countries, is related to accreditation by administrative means: since 2013 a mandatory condition for obtaining a higher accreditation category for secondary and tertiary medical care institutions is the presence of a certificate of compliance of the institution's quality management system with the requirements of the national standard DSTU ISO 9001 series. This requirement is preserved even when accreditation is introduced on voluntary terms. The mandatory nature of the certification leads the managers of health care institutions to formally implement the quality management system with the aim of obtaining a certificate, rather than improving the quality of medical care.

Thus, the analysis of the features of the application of world practices for regulating the quality of medical care in Ukraine proved:

- excessive administrative influence on licensing, accreditation, certification procedures;
- from the year 2018 discontinuance of the movement towards the introduction of licensing of the professional practice of doctors;
- after 2015 slowdown of the development of the national system of standardization of medical technologies;
- obsolescence, low quality of accreditation standards in terms of content, scope, methodology of development, implementation and monitoring of compliance; their formal character;
- lack of mechanisms to motivate health care institutions to constantly improve the quality of medical care through accreditation and certification of the quality management system.

In view of the above, the conceptual directions for improving the tools for regulating the quality of medical care in Ukraine: regulatory and legal regulation, functional and organizational changes, informational and methodological, personnel support and the use of advanced tools for monitoring and assessments of the quality of medical care are presented in the Figure.

Purpose: to substantiate the conceptual directions of improvement of approaches to the regulation of the quality of medical care in Ukraine



Conceptual directions for improving the tools for regulating the quality of medical care in Ukraine

CONCLUSIONS

1. Ukraine uses tools for regulating the quality of medical care, the effectiveness of which has been proven by long-term international practice: licensing of medical practice, accreditation of health care facilities, standardization of medical technologies, certification of quality management systems. At the same time, in terms of subjects and objects of regulation, content, scope, methods of implementation, use and monitoring of the relevant standards, these instruments require revision, updating and approximation to international practices, which will contribute to improving the quality of medical care for the population.

2. Prospects for further research lie in observing and evaluating the effectiveness of improved tools for regulating the quality of medical care in Ukraine.

Contributors:

Tolstanov K.O. – management;

Krut A.G. – conceptualization, methodology, visualization, finding financial support, writing – reviewing and editing;

Dmitrenko I.A. – curation of data, writing-initial project;

Gorachuk V.V. – project administration.

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